

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

: CIVIL ACTION NUMBER:
: 19-md-02875
IN RE: VALSARTAN PRODUCTS :
LIABILITY LITIGATION :
: DEPOSITION DESIGNATION
: HEARING VIA TEAMS

Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101
September 26, 2024
Commencing at 9:37 a.m.

B E F O R E: **THOMAS I. VANASKIE (RET.)**
 SPECIAL MASTER

A P P E A R A N C E S:

MAZIE SLATER KATZ & FREEMAN, LLC
BY: ADAM M. SLATER, ESQUIRE
103 Eisenhower Parkway
Roseland, New Jersey 07068
For the Plaintiffs

KANNER & WHITELEY, LLC
BY: DAVID J. STANOCH, ESQUIRE
701 Camp Street
New Orleans, Louisiana 70130
For the Plaintiffs

Sharon Ricci, CRR, RMR, Official Court Reporter
sharon.ricci.usdcnj@gmail.com
(267) 249-8780

Proceedings recorded by mechanical stenography; transcript
produced by computer-aided transcription.

A P P E A R A N C E S (Continued):

NIGH GOLDBERG RASO & VAUGHN
BY: DANIEL A. NIGH, ESQUIRE
1333 College Parkway, #1049
Gulf Breeze, Florida 32563
For the Plaintiffs

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
BY: NINA ROSE, ESQUIRE
1440 New York Avenue, N.W.
Washington, DC 20005
For the Defendants Princeton Pharmaceuticals,
Solco Healthcare U.S. LLC, and Zhejiang Huahai
Pharmaceuticals Ltd.

GREENBERG TRAURIG LLP
BY: VICTORIA DAVIS LOCKARD, ESQUIRE
3333 Piedmont Road, NE, Suite 2500
Atlanta, Georgia 30305
Counsel for the Defendant, Teva Pharmaceutical Industries
Ltd., Teva Pharmaceuticals USA, Inc., Actavis LLC, Actavis
Pharma, Inc. (Collectively Teva)

KIRKLAND & ELLIS, LLP
By: JACOB M. RAE, ESQUIRE
601 Lexington Avenue
New York, New York 10022
For the Defendants Torrent Pharma, Inc.
and Torrent Pharmaceuticals Ltd.

ALSO PRESENT:

Loretta Smith, Judicial Law Clerk

Larry Macstravic, Courtroom Deputy

1 (PROCEEDINGS held via Teams Conference before Special
2 Master Thomas I. Vanaskie at 9:37 a.m.)

3 SPECIAL MASTER VANASKIE: So we're on the record.
4 We're going to first address the objections to the designations
5 of the deposition testimony of Claire Lyons. And there are
6 both objections with respect to plaintiffs' designations and
7 defendant's counter-designations and we'll proceed sequentially
8 through those objections, I hope.

9 Let me tell you what I have and then we can see if we
10 are all on the same page.

11 I'm going to -- so the first objections I have with
12 respect to plaintiffs' affirmative designations starts at
13 page 48, line 2, and continues over to 48, line 16.

14 Are we all on the same page with respect to that?

15 MR. STANOCH: Correct, Your Honor, for plaintiff.

16 MS. LOCKARD: I apologize. I just cannot even get an
17 Excel to open. I've got the transcript, though. Okay. 48-2
18 to 48-6. That's right, that's the first line.

19 SPECIAL MASTER VANASKIE: And that's the question and
20 then the answer goes from lines 9 to 16.

21 MS. LOCKARD: Correct. Okay.

22 So the issue with this, essentially, Your Honor, is
23 that the question itself, he's asking about the purpose of the
24 GMP requirements to ensure manufacturing facility, and to
25 decrease the likelihood that the facility may release a

1 defective product.

2 We objected to this because we think it's irrelevant
3 and it's confusing and misleading to the jury. This is not a
4 product defect case. There are no allegations in the case of a
5 defective product. This is an express warranty case, a fraud,
6 and consumer protection case. And so there's no testimony by
7 any expert in this case about whether the product was defective
8 or not.

9 So I think this question and the answer are misplaced,
10 confusing, and it's really irrelevant to the issues that we're
11 trying in this TPP case.

12 SPECIAL MASTER VANASKIE: All right. David?

13 MR. STANOCH: Thank you, Your Honor.

14 First, with Ms. Lyons, just so Your Honor knows,
15 there's very little testimony we even designate, there's only
16 maybe two -- maybe three clips that we want to play of her. So
17 this is just one of the two or three. Right?

18 SPECIAL MASTER VANASKIE: Right.

19 MR. STANOCH: So I just wanted to give that context of
20 how focused our designations are because Your Honor only sees
21 the disputed one.

22 The question obviously is asking a Teva quality
23 executive, who's been at Teva's quality department her entire
24 career, about the purpose of GMP requirements regarding
25 manufacturing facilities, and that's exactly what we're

1 presenting to the jury in a month.

2 She answers the question, she explains what the
3 purpose of the GMP requirements are to her, and she has no
4 difficulty in answering it.

5 Ms. Lockard seems to think there's some issue with the
6 word "defective" being use in the question.

7 First of all, Ms. Lyons doesn't say anything about
8 defective in her answer. So any confusion that she thinks may
9 arise is not arising of this, number one.

10 Number two, we're not using this as a term of art as a
11 product defect/product liability claim, Your Honor. The FDA
12 regulations and FDA documents, which both sides will be
13 submitting into evidence for the jury, are rife with references
14 to quote/unquote defective or possibly defective or possibly
15 flawed product, right, just to describe something that's not
16 made in compliance.

17 I mean, the FDA website, for example, talks
18 about recalls about -- recalls happening because a drug is
19 defective or flawed, could be hazardous to health. We're not
20 trying to prove, quote, defective, but in the ordinary laymen's
21 way of understanding it, this was a product that had an actual
22 defect in it, the nitrosamines, and the GMP requirements are
23 supposed to decrease the likelihood of them having defects in
24 them.

25 SPECIAL MASTER VANASKIE: Yes, I understand your

1 arguments. I've -- I hope you all don't take this the wrong
2 way, but I think, you know, when you have the opportunity to
3 look at a cold transcript and dissect each word, it all of a
4 sudden becomes problematic.

5 I don't view this question as problematic. I don't
6 think it calls for speculation. I don't think it's vague. So
7 the objection is overruled. I think it's a proper question.

8 MR. STANOCH: Thank you, Judge.

9 SPECIAL MASTER VANASKIE: All right.

10 MS. LOCKARD: Thank you, Judge. I think that was the
11 only issue for her.

12 SPECIAL MASTER VANASKIE: I think so, except for the
13 counter-designations, defendant's affirmative designations.
14 Let me pull up my spreadsheet because the printout didn't help
15 me out at all.

16 So this now deals with defendant's affirmative
17 designations. The first one starting on page 15 of Claire
18 Lyons' testimony at lines 21 going to page 16, line 12; then
19 18, line 17 to page 19, line 11; page 22, lines 3 to 14.

20 The objection is unavailability. I don't know what --
21 you also have issue of when and how to play. I'm not sure what
22 this means, David.

23 MR. STANOCH: Yes, Judge.

24 And, essentially, plaintiffs believe that there's
25 still an open issue with Judge Bumb about when and whether and

1 in what chronology defendants may play their affirmative
2 designations. I don't think you need to address these, Your
3 Honor. I think when we put that in, that's a placeholder for
4 that issue.

5 For example, I assume Ms. Lockard wants -- if I play
6 page 14 of Ms. Lyons, she wants her counter, or her affirmative
7 on page 15 to come right next, right, when the jury sees it,
8 versus my clips playing, then her clips playing.

9 And I think there's a little uncertainty on that for
10 all parties. So this is just sort of a placeholder objection.
11 I don't think there's anything substantive for Your Honor to
12 rule at this point.

13 SPECIAL MASTER VANASKIE: Seems to be the trial judge
14 prerogative on that.

15 Let me ask you just one quick question on the
16 unavailability issue. Are you asking me to decide that or is
17 that being deferred to Judge Bumb?

18 MR. STANOCH: Unless someone on my side disagrees with
19 me, I think that's for Judge Bumb. I think defendant's view is
20 if Judge Bumb said plaintiffs can play videos, they can
21 designate affirmatively from the same transcript video. I
22 think we have a technical objection that it's their witness and
23 they haven't proven that the witness can't show up in their
24 case so the normal rule is we can play a party opponent
25 admission and then in their case, they can call their witness.

1 But I think that's for Judge Bumb at this point.

2 SPECIAL MASTER VANASKIE: Yes, I think so. The
3 unavailability issue I believe is also for Judge Bumb, so we
4 won't address that.

5 Looking at the spreadsheet with the objections, the
6 objections that I believe I should be able to handle deal with
7 testimony at page 76, lines 9 to 23 of Claire Lyons' testimony.
8 Let me pull that up.

9 So the question is: Were you suggesting here that
10 Teva should have an NDMA impurity testing method for incoming
11 valsartan API?

12 And the objection is relevance, misleading, lack of
13 foundation, lacks personal knowledge, speculation.

14 MR. STANOCH: Yes, Your Honor. I'm happy to go first
15 here on this one, unless you otherwise --

16 SPECIAL MASTER VANASKIE: Yes, it's your objection.

17 MR. STANOCH: The testimony is about a specific
18 document, and this testimony comes in in the middle of a long
19 line of questioning about a specific document.

20 So in one sense it's simply jumping into something
21 that we didn't put in in our case or have a designation on
22 about the testing method, so it just sort of injects now for
23 the first time, oh, were you suggesting that Teva should have a
24 method, based on the reading of the document, and she said, no,
25 that's not what I meant in the document, right?

1 So without the context, it has no relevance, it's
2 confusing, it's misleading, et cetera. That's number one.

3 Number two is, there's a number of times where the
4 witness gratuitously adds information that she has no personal
5 knowledge or speculation on. For example, right below on that
6 page, she answered the question, yes, that's correct, but then
7 throws in, nobody -- no pharmaceutical company had a testing
8 method at the time.

9 And if you read down some more in this questioning, in
10 our counters, if Your Honor would let this in, she actually
11 says on page 78, yeah, okay, so it's fair to say that that's
12 speculation on my part. I don't know for a fact and I can't
13 confirm the fact.

14 So she herself is saying she doesn't know about what
15 she's talking about here in these questions and answers, which
16 we think, you know, makes it inadmissible from the get-go.

17 But if Your Honor is going to let it in, we think the
18 other context of our completeness designations around that very
19 precise line that makes clear she's speculating should, in
20 fairness, come in.

21 SPECIAL MASTER VANASKIE: All right. Victoria?

22 MS. LOCKARD: Well, on the speculation part, Your
23 Honor, she does clarify, and if the counter comes in, she
24 clarifies that it was knowledge within the industry that there
25 wasn't a testing method. And while -- when you take this clip

1 itself as if there has been no foundation throughout the
2 case -- which by the time this is played, these issues will
3 have already been presented through the evidence -- it is
4 directly on point to the issues in this case, it is something
5 that is not out of context in the whole of the evidence that
6 will be presented.

7 And if we were to bring this witness live, which
8 initially Judge Bumb had said that plaintiffs needed to bring
9 all the witnesses live and then said that, you know, they could
10 play video testimony in the interest of moving the case along
11 more efficiently, in order to keep the case cut down in a
12 manner so we could actually get it tried in the allotted time,
13 we want to play these affirmatives.

14 This is information that we would pull out if the
15 witness were brought live and plaintiffs and defendants were
16 questioning the witness on the stand.

17 I mean, this is a core question in the case itself as
18 to whether or not Teva should have had a testing method, and if
19 they didn't, which they didn't, why they didn't. And the
20 reason they didn't was because the industry hadn't developed
21 one yet. And she is an important quality witness who addresses
22 this point in her deposition.

23 So I don't have a problem with the counter if they
24 want to play that, but, you know, they initially had included
25 all of this in plaintiffs' own affirmatives and then they took

1 it out.

2 And so we're simply trying to put back in some of the
3 affirmative testimony on the issues that she was designated on,
4 that she testified on, and that are directly relevant to the
5 case, which is, why weren't the industry defendants testing for
6 these drugs?

7 So there will be a foundation laid, it will clearly be
8 presented by the time this witness testifies. It's not taken
9 out of context and it's directly on point.

10 SPECIAL MASTER VANASKIE: All right. My preliminary
11 determination is now going to be my final determination, and
12 that is to allow the counter to come in. So the defendant's
13 affirmative designation would come in as well as the
14 plaintiffs' counter-designation. This deals with -- so I guess
15 the record is clear on this, this deals with the testimony --
16 questioning and testimony from page 76, line 9 to 76, line 23.

17 You would also have the counters which come in at
18 page 73, line 11 to 75, line 2; 75, line 13 to 19.

19 MR. STANOCH: 3 to 19, I think, Your Honor.

20 SPECIAL MASTER VANASKIE: What's that?

21 MR. STANOCH: 3 to 19. You said 13, Your Honor. I'm
22 sorry.

23 SPECIAL MASTER VANASKIE: You're straining my eyes
24 here.

25 Yes, 3 to 19. 75, line 23 to 76, line 8; 76, line 24

1 to 77, line 1; 77, line 4 to 78, line 4; and 79, lines 22 to
2 24.

3 Also coming in would be the defendant's affirmative
4 designation at 79, lines 15 to 21.

5 MR. STANOCH: Understood, Judge. Thank you.

6 SPECIAL MASTER VANASKIE: All right. That takes care
7 of that.

8 Let's go to the next series beginning on page 80,
9 line 1 -- this is the defendant's designation. And the
10 question is: And as of the date of this email, June 29, 2018,
11 had Teva placed a hold on the distribution of any finished dose
12 product with valsartan API yet?

13 The objection is on relevance grounds. There's a
14 counter that would extend that designation to 89 -- plaintiffs'
15 designation would be 89, lines 1 to 18.

16 My inclination is to allow both, allow the counter.
17 Why would that be wrong?

18 MR. STANOCH: Plaintiffs are fine with that, Your
19 Honor.

20 SPECIAL MASTER VANASKIE: I don't see any objection to
21 the counter, so I take it you're all right with that, Victoria?

22 MS. LOCKARD: Well, Your Honor, the first time I saw
23 the objections to our affirmatives are when he emailed you the
24 spreadsheet.

25 SPECIAL MASTER VANASKIE: Okay.

1 MS. LOCKARD: So I saw the objections to the
2 counters -- or to our affirmatives yesterday. And I can tell
3 you I still can't even open up the spreadsheet right now to see
4 what they are. I looked at them yesterday, last night,
5 obviously, but I don't know what's wrong with my system, so...

6 SPECIAL MASTER VANASKIE: I think maybe the best way
7 to handle this would be to give you the opportunity to seek
8 reconsideration of rulings that I'm making.

9 As I said, I don't see objections to the counter. But
10 you may not have had an opportunity to articulate those
11 objections, so we'll give you that opportunity. But right now
12 I would allow the testimony from page 80, lines 1 through 7,
13 and on page 89, lines 1 through 18.

14 MR. STANOCH: Plaintiffs are fine to proceed that way,
15 Judge.

16 MS. LOCKARD: Your Honor, I would ask that we just --
17 I need an opportunity to be able to look at what we're ruling
18 on and discussing. And I apologize that I have a technical
19 issue where I cannot pull these up, but I would like to ask
20 that you give me an opportunity to pull up these objections and
21 respond to them.

22 In fact, I -- we -- in the prior witness for Teva, we
23 did not discuss Teva's affirmatives because we were waiting on
24 this issue as to whether or not plaintiffs are even going to
25 be -- were even going to be able to play our affirmatives in

1 their case.

2 So, frankly, I was not anticipating addressing our
3 affirmatives for her today. I can't pull them up because of
4 technical difficulties and I haven't had a chance to even
5 provide any counters on paper because Mr. Stanoch
6 submitted this before he even showed me what his counters
7 were.

8 SPECIAL MASTER VANASKIE: All right. We'll defer
9 consideration of these --

10 MS. LOCKARD: I'll get you our objections to the
11 affirmatives by the end of today, Judge, and then we can -- if
12 this is all right with you, we can knock this out for Ms. Lyons
13 tomorrow.

14 SPECIAL MASTER VANASKIE: Yes, we'll give it a shot
15 tomorrow.

16 I will tell you now so you -- I think this is
17 appropriate -- that my inclination was to allow the Teva
18 designations and the affirmative counter-designations. So you
19 can look at it with that understanding in mind.

20 But no ruling will be made until you've had a chance
21 to articulate your position, especially with respect to the
22 counters.

23 All right?

24 MS. LOCKARD: I appreciate it. Thank you, Judge. And
25 I apologize for the technical issues.

1 SPECIAL MASTER VANASKIE: All right. Should we
2 continue on to the next Teva witness or is Mr. Slater here with
3 respect to the ZHP witnesses? I don't see him on my screen.

4 MR. STANOCH: I'm fine to go to a Teva witness,
5 Your Honor, provided Ms. Lockard has her tech issues under
6 control.

7 MS. LOCKARD: I do have for Mr. Vadsola and Pan Lin,
8 and I should be able to proceed.

9 SPECIAL MASTER VANASKIE: Okay. Let's proceed to
10 Mr. Vadsola. Give me a second to pull up the spreadsheet.

11 We'll start with plaintiffs' disputed designations,
12 and we have counter-designations from the defendant with
13 plaintiffs' response to counter-designations.

14 I believe we start at page 52, line 12 and proceed to
15 page 53, line 3 on the plaintiffs' affirmative designations,
16 and then we have counter-designations at 53, lines 4 to 7 and
17 53, line 12 to 54, line 7.

18 So let me get the testimony in front of me.

19 So I didn't see any objection to the plaintiffs'
20 affirmative designation but I did see plaintiffs disputing the
21 counter-designations.

22 MS. LOCKARD: I think that's correct.

23 MR. STANOCH: I agree.

24 SPECIAL MASTER VANASKIE: And your objection or
25 response is that the counter-designations are not necessary for

1 completeness?

2 MR. STANOCH: That's right, Your Honor. Simply put,
3 this is just a background section of who this witness is.
4 Right? We want to get in, we designate just sort of the key
5 points of his background, when he was testifying early, and
6 then want to get right into the testimony.

7 And the counters add, you know, another page or more
8 of testimony about his background that we don't think is really
9 pertinent or not necessary for completeness.

10 SPECIAL MASTER VANASKIE: Victoria, do you want to
11 respond?

12 MS. LOCKARD: Yes, Your Honor.

13 We think -- so this is a witness who's limited to
14 speaking on the audits that Teva did at the ZHP facility. And
15 without providing background as to what Mr. Vadsola's role is
16 and what he does at Teva, it is going to be difficult for the
17 jury to take in this witness's testimony. It's going to be
18 confusing. They're going to wonder who is he and how does this
19 fit in?

20 So there's nothing really controversial about it, but
21 we think that they should be provided a little bit more
22 information about Mr. Vadsola and his group before they start
23 talking about the actual audit details.

24 I mean, they don't know if this is related to FDA, is
25 this -- you know, how does this work? And so this is just

1 non-controversial background information to help the jury
2 understand the testimony that's flowing from it.

3 SPECIAL MASTER VANASKIE: All right. I will allow the
4 counter-designation. So the testimony at page 53, lines 4
5 to -- lines 4 to 7 and 53, line 12 to 54, line 7 will come in.

6 Let's go to the next designation. Again, there's no
7 objection to the plaintiffs' affirmative designation. There is
8 an objection on completeness grounds with respect to the
9 testimony at page 55, lines 15 to 20, and page 56, lines 13 to
10 20.

11 MS. LOCKARD: Your Honor, I -- we actually withdrew
12 these counters already. I think that maybe got lost somewhere
13 in the Excel transmissions, but we did withdraw those so --

14 SPECIAL MASTER VANASKIE: Oh, good, because I was
15 going to disallow them so --

16 (Laughter.)

17 MS. LOCKARD: I would not fight you on that ruling,
18 Your Honor, so we can move on.

19 SPECIAL MASTER VANASKIE: All right. Where is -- does
20 that take us now to page 63, lines 7 to 13?

21 MS. LOCKARD: Yes.

22 SPECIAL MASTER VANASKIE: And your counter-designation
23 is page 71, line 18 to 72, line 11.

24 MS. LOCKARD: That's correct.

25 SPECIAL MASTER VANASKIE: I take it you didn't

1 withdraw that one?

2 MS. LOCKARD: We did not, Your Honor.

3 SPECIAL MASTER VANASKIE: All right.

4 MR. STANOCH: Your Honor, I guess because it's our
5 objection to the completeness counter, you'll see the actual
6 designations and questions is a series of back and forth with
7 the witness about a particular Teva SOP regarding audits,
8 right? And then it stops at 67-13.

9 And then what Teva wants to designate for completeness
10 jumps pages later about what CAPA, C-A-P-A, stands for, and
11 what CAPA means, and it has nothing to do with the SOP sections
12 that we were asking about pages earlier.

13 SPECIAL MASTER VANASKIE: Yes, why do we need to have
14 this come in, Victoria?

15 MS. LOCKARD: Essentially, Your Honor, plaintiff is
16 asking about the policy that relates to the audit process. The
17 completeness counter explains what the response by the audited
18 company is.

19 So it does flow from the initial -- from the
20 designation because they're asking about the audit policy. And
21 part of the process is that the audited company provides a
22 response, which is the CAPA. So we feel that in fairness, it
23 provides -- (Audio interruption.)

24 MR. STANOCH: I lost Ms. Lockard.

25 MS. LOCKARD: Can you hear me?

1 MR. STANOCH: Yes.

2 SPECIAL MASTER VANASKIE: Yes.

3 MS. LOCKARD: Did you hear my response? It was
4 amazing.

5 (Laughter.)

6 SPECIAL MASTER VANASKIE: I heard your response. I
7 was persuaded by it.

8 Do you want to say anything else, Mr. Stanoch?

9 MR. STANOCH: I would.

10 Your Honor, CAPA does not appear at all in this
11 transcript until the counter-designation for completeness that
12 they're talking about. They just jump in and now want -- the
13 only designation they have is what does CAPA stand for and what
14 a CAPA is.

15 There's no discussion about that at all. The phrase
16 doesn't appear at all.

17 In fact, Teva's skipping over the part immediately
18 before their completeness designation on that same page where
19 CAPA finally does come up.

20 So Ms. Lockard likes to say it's going to be confusing
21 for the jury to understand what's going on, I think it's going
22 to be confusing for a jury to hear about an SOP about audits
23 and then all of a sudden hear: CAPA stands for corrective
24 preventive action. It's not tethered to anything.

25 MS. LOCKARD: And we actually -- we did not designate

1 the response about what CAPA actually stands for. We simply
2 designated the question, Mr. Stanoch's question and the
3 witness's response, about the response by the audited entity
4 being a CAPA.

5 And that is important because plaintiff is asking
6 about the policy, the auditing policy, and then there's no
7 follow-up in terms of, well, the response by the ZHP audited
8 entity.

9 So it does make sense and it flows from that and it
10 was Mr. Stanoch's question right after that segment. So it
11 certainly is a completion to the initial questions about the
12 audit policy.

13 MR. STANOCH: Everything is completeness, Your Honor.
14 If there's something where I question at another point
15 immediately before it, then the whole transcript is going to
16 come in if that's the rule, and it's not.

17 (Simultaneous speakers.)

18 SPECIAL MASTER VANASKIE: You get to make your
19 designations, they get to make counters, and they can argue
20 completeness. And in this instance I am persuaded that it
21 would be necessary for completeness.

22 So the objection, to the extent there is an objection,
23 on the grounds that it's not necessary for completeness, is
24 overruled. The testimony at page 71, line 18 to 72, line 11
25 will come in.

1 According to -- I think we now move to page 105, lines
2 5 to 12. This is an objection to the plaintiffs' designation.
3 Let me get the testimony in front of me.

4 I know I needed a third monitor and I don't have a
5 third monitor.

6 MS. LOCKARD: That would be helpful.

7 So, Your Honor, just to orient you on the issues that
8 pertain to the next couple of designations. So Mr. Vadsola is
9 an auditing manager at Teva and what he's testifying primarily
10 about are various audits that Teva did of its supplier, ZHP.
11 And some of these audits are relevant to this case, some of
12 them are not.

13 And so what you're going to see in the disputes
14 over Mr. Vadsola -- and also Pan Lin's deposition, because he
15 was also on the audit team -- is which of these audits come in
16 and which do not. And so there were audits predating even --
17 and this is one, predating Teva even using ZHP's valsartan
18 API.

19 So this is regarding a September 2011 audit that is a
20 for-cause audit that relates to other issues. Teva wasn't even
21 using ZHP's API when this audit was done, and so how could it
22 be relevant?

23 Judge Bumb in her motion in limine rulings made very
24 clear that audits of regulatory activities that relate to
25 valsartan and relate to the process at issue and relate to the

1 facilities that made that valsartan that is at issue in this
2 case are relevant. But if there's anything else, you can't
3 just throw in audits and regulatory activities, what she called
4 essentially being a character assassination, those were her
5 words.

6 And so plaintiffs can't bring up every audit that was
7 done or every regulatory inspection to say look at all of these
8 bad things and bad observations at the ZHP facility that Teva
9 or somebody else saw.

10 So we have to be particular in which of those are let
11 in and which aren't, because it's going to be highly
12 prejudicial. It is going to be confusing and misleading to the
13 jury to hear about all of these audits about issues that are
14 not relevant to this case.

15 The testimony that you're looking at is regarding the
16 2011 September audit, and it falls under that heading of not
17 relevant because it doesn't relate to the API valsartan at
18 issue.

19 SPECIAL MASTER VANASKIE: All right.

20 David?

21 MR. STANOCH: Your Honor, we're not trying to lob in
22 information about audits of facilities in Africa that made
23 band-aids, not drugs. We're not talking about someone dropped
24 some glass in a batch of opioids in a factory in Greenland.
25 None of that is happening with Mr. Vadsola.

1 The audit hub manager of Teva for the Asia region, all
2 right, overseeing auditors who audited facilities in Asia,
3 including China, including ZHP, this audit is highly relevant.
4 It specifically has to do about a for-cause urgent audit, their
5 words, urgent audit regarding valsartan API.

6 And the issue in the cover email -- and I know Your
7 Honor doesn't have it, is the Teva personnel saying there's a
8 serious failure about ZHP at the Chuannan site, which, by the
9 way, is the exact site at issue in this case that made the
10 valsartan API, right, for the Teva product that's at issue and
11 for ZHP's own product that's at issue, right, that says there
12 was serious failure for their change control procedure.

13 One of the things that Your Honor has heard in the
14 context of ZHP is that the FDA noted eventually that ZHP's
15 change control procedures and processes were insufficient when
16 they changed the manufacturing process.

17 So here we have as early as 2011, right, when Teva is
18 buying product, by the way, valsartan, from this facility,
19 albeit not for a certain other factory of it, but Teva is using
20 this valsartan. And it sent its auditors in, and they say, we
21 have an issue with ZHP Chuannan site's change control
22 procedures as to valsartan.

23 I cannot see how this is -- this is not a character
24 assassination. This is core evidence, Judge.

25 And Ms. Lockard herself says you have to connect that

1 -- Judge Bumb said that you need to connect the dots to
2 valsartan or the facility at issue. This does both.

3 MS. LOCKARD: And we disagree. The issue in this
4 audit related to a particle size issue, which has nothing to do
5 with the allegations in this case. And it doesn't have to do
6 with the valsartan API that was being purchased and sold that
7 is the subject of this case.

8 So just because you point to a process change, which
9 has nothing to do with the process change that's at issue in
10 this lawsuit, and just because that facility was making
11 valsartan for other purposes, not for the purposes of the drugs
12 that were sold at issue in this lawsuit, does not connect the
13 dots sufficiently. That's our position.

14 SPECIAL MASTER VANASKIE: Yes, I -- my initial
15 inclination was to allow this. I believe my initial
16 inclination was correct. I think it is sufficiently tied, the
17 dots are sufficiently connected to allow this testimony to come
18 in.

19 MS. LOCKARD: Okay. I appreciate that, Judge. I
20 understand your ruling. I am looking at what that may impact
21 because it may impact some of the additional designations.

22 SPECIAL MASTER VANASKIE: Yes, that's what I'm trying
23 to do too.

24 MR. STANOCH: And I'm not rushing Ms. Lockard, Your
25 Honor. She can obviously take the time that you need.

1 But I think this line of questioning that's disputed
2 about this audit in 2011 looks like it runs through 110-5 to
3 110-8.

4 SPECIAL MASTER VANASKIE: So --

5 MS. LOCKARD: I agree with that. I agree with
6 Mr. Stanoch.

7 SPECIAL MASTER VANASKIE: Yes. And my notes indicated
8 to allow all of that, so I guess to be clear on this, I would
9 allow the testimony from page 105, line 5 to 106, line 12;
10 page 107, line 5 to page 107, line 13; page 108, line 2 to
11 page 110, line 2; page 110, line 5 to page 110, line 8.

12 So that takes us now to page 112, line 22 and the
13 counter-designation at page 113, line 14 to 21.

14 So really what's at issue here is that -- I guess it's
15 both, there was an objection that the questioning called for
16 speculation and then there was an objection that the counter
17 was not necessary for completeness.

18 MS. LOCKARD: Right. And I think our position on this
19 one, Your Honor, was that we would withdraw the objection if
20 plaintiffs would agree to the counter of lines 14 to 21, and
21 they did not agree.

22 MR. STANOCH: One moment, Your Honor.

23 SPECIAL MASTER VANASKIE: Yep.

24 MR. STANOCH: 113-14 is in the middle of an answer, I
25 think, Ms. Lockard?

1 MS. LOCKARD: That should have been 112-14 to 21.

2 MR. STANOCH: 112 to 21?

3 MS. LOCKARD: Right.

4 MR. STANOCH: That's an answer, not a question then.

5 I mean, if you want the -- you want the question at 113-9
6 through 21, is that -- oh, that's not right either. I guess
7 I'm not lighting up, Ms. Lockard. I'm sorry.

8 MS. LOCKARD: The counter was page 112, line 14 to 21.

9 MR. STANOCH: Oh, I see.

10 MS. LOCKARD: And I guess that became 113 somehow. I
11 think that's just a --

12 SPECIAL MASTER VANASKIE: A typo?

13 MS. LOCKARD: -- a typo error. But the point is, you
14 know, we objected because he's being asked about an audit that
15 he wasn't involved in. The counter simply makes clear, look,
16 you weren't involved in this audit. So --

17 MR. STANOCH: Your Honor, that's fine. With the
18 objection withdrawn, we will withdraw our objection to the
19 counter.

20 SPECIAL MASTER VANASKIE: Okay.

21 MR. STANOCH: So I think everything comes in.

22 MS. LOCKARD: Okay.

23 SPECIAL MASTER VANASKIE: So by everything, we mean
24 the testimony at page 112, lines 14 to 21; page 112, lines 22
25 to page 113, line 8. All right?

1 MS. LOCKARD: Yes.

2 SPECIAL MASTER VANASKIE: So this takes us now to
3 page 131, line 12. My notes say it starts with line 5.

4 MR. STANOCH: You're right, Your Honor. That
5 should -- the question would be at 131-5 through 9, so I think
6 for sure that would be part of what we would need to designate
7 as well. Apologies.

8 SPECIAL MASTER VANASKIE: Okay. Are you with us,
9 Victoria?

10 MS. LOCKARD: Yes. So we added back in the answer at
11 line 5, which is one issue --

12 MR. STANOCH: The question, sorry.

13 MS. LOCKARD: Excuse me, the question, yes. And then
14 that resolves, I think, our objection.

15 But then we had a counter of 132, line 8 to 22. This
16 is a continuation essentially of his answer. And if necessary,
17 we could add in Mr. Stanoch's question here, but this is a
18 completion and continuation of the answer.

19 SPECIAL MASTER VANASKIE: Yes. So the record is
20 clear, what will come in is the testimony starting on page 131,
21 line 5 through 132, line 22.

22 Does everybody agree? You can take out the
23 objections.

24 MR. STANOCH: Of course. I think that's right, Your
25 Honor.

1 MS. LOCKARD: Yes.

2 SPECIAL MASTER VANASKIE: All right. So I believe
3 we're now to page 135, line 15.

4 MR. STANOCH: 135, 2 through to -- I think it begins
5 at 2 through 5 there, Judge.

6 SPECIAL MASTER VANASKIE: 135, 2 through 5, that is
7 correct.

8 MR. STANOCH: And then the ensuing lines are questions
9 about another Teva audit report of ZHP dated August 2016, yes,
10 that's correct.

11 MS. LOCKARD: All right. This involves another audit
12 report, Your Honor, from 2016. And unlike the prior audit --
13 and I understand your rulings and you're setting some
14 parameters here, but this particular audit does not involve
15 valsartan at all. Not just the valsartan in the case, it
16 doesn't involve valsartan at all.

17 It is an audit of the facility where the valsartan was
18 made, true, but it's not an audit that involves these products.

19 And Judge Bumb's ruling on that motion in limine
20 specifically said if it doesn't involve these products, it's
21 out. So we maintain that any testimony related to that 2016
22 audit should come out.

23 SPECIAL MASTER VANASKIE: David?

24 MR. STANOCH: Your Honor, we heard at the 2011 audit
25 from Ms. Lockard -- and the record will correct me if I'm

1 wrong -- that information of audits relating to valsartan or
2 the facilities at which the valsartan was made are fair game,
3 and otherwise plaintiffs can connect the dots.

4 And Ms. Lockard concedes, rightly so, that this audit
5 by Teva of ZHP is, again, of the Chuannan site facility of ZHP,
6 the one that made the valsartan.

7 So facially it satisfies even what Ms. Lockard says
8 Judge Bumb says.

9 Number two, the testimony designated is very narrow.
10 We're not looking through this report and asking questions and
11 trying to say, oh, you didn't keep a reserve sample of generic
12 aspirin or something like that. It's focused specifically on
13 quality control and analytical equipment issues, and more
14 specifically, of findings by Teva that there were no
15 appropriate -- I'm paraphrasing -- there were no appropriate
16 records for integration of HPLC/GC chromatograms and other
17 issues regarding the chromatograms and data integrity use of
18 testing generally.

19 That's one of the core issues in this case, later
20 found that the evidence we think will show, right, that ZHP's
21 quality systems, specifically those regarding its quality
22 control and analytical assessments, are relevant, that they
23 could have caught the issue sooner. Or at the very least,
24 Teva, in knowing that ZHP, at the very facility making the
25 valsartan, was having quality issues with its systems regarding

1 the handling of chromatograms, that that should have raised the
2 antenna of Teva to probe and ask more questions and look a
3 little deeper and they could have discovered -- a jury could
4 certainly find, discovered some of the issues earlier about
5 ZHP's valsartan, just like Novartis did when they looked at the
6 chromatograms that ZHP gave them and said, hey, wait a minute,
7 there's something here.

8 So we think this is highly relevant, falls within the
9 scope of even what Ms. Lockard says Judge Bumb says. And the
10 testimony is all narrowly focused on those issues.

11 SPECIAL MASTER VANASKIE: Victoria.

12 MS. LOCKARD: Your Honor, I think Mr. Stanoch
13 misunderstood what I said. And maybe the transcript -- if I
14 misspoke, then I will own that. But it has to be -- this is
15 from Judge Bumb. It has to be from the facility that's at
16 issue, the Chuannan facility, and it has to be related to
17 valsartan.

18 I'm not conceding that anything in all audits and
19 issues at that facility in Chuannan are relevant. We made this
20 exact argument to Judge Bumb at the motion in limine hearing.
21 Judge Bumb specifically said -- and I mean, I'm quoting her --
22 she said: If it's the same facility, it still has to be a
23 connection to valsartan more directly. It can't be an entire
24 sort of a character assassination.

25 And this was the exact argument you're hearing from

1 Mr. Stanoch that he made to Judge Bumb at the motion in limine
2 hearing, and it was shot down by Judge Bumb. So --

3 MR. STANOCH: I disagree it was shot down, Your
4 Honor.

5 If Ms. Lockard reads the rest of the transcript, I
6 jumped up and said, Your Honor, it can't be limited to just
7 valsartan because the way these companies do GMP oversight,
8 right, there's systemic and systematic issues.

9 And, Judge, I don't have it in front of me, but Judge
10 Bumb says, well, that's different. That could be more
11 probative, connect your dots.

12 Again, we're talking about a systemic issue at the
13 very facility that made this valsartan API about its quality
14 control, more specifically about analytics, more specifically
15 about chromatograms.

16 So I think that certainly satisfies whatever
17 Ms. Lockard characterizes Judge Bumb as saying, and I'm sure
18 Judge Bumb at the time, on the very first time she heard us all
19 in person about this case, was not thinking at this particular
20 level of detail when she might have made statements that, in
21 part, only Ms. Lockard read to you.

22 MS. LOCKARD: So what Mr. Stanoch is saying is that if
23 the audit relates to quality control issues, then it's
24 relevant. Every audit relates to quality control issues.
25 That's what an audit is.

1 So it has to be a systemic issue that is relevant to
2 the problems that led to the nitrosamine impurity. You can't
3 just say, well, they had a quality control issue related to
4 their equipment or related to their testing if you don't show
5 that that exact problem that Teva was complaining of in the
6 audit is relevant or would have prevented or had anything to do
7 with what ultimately led to nitrosamines.

8 MR. STANOCH: Your Honor, I'm not using "quality
9 control" generally. I'm using the words on Teva's own audit
10 report. It has multiple specific sections, and this is the
11 section, it's only two pages, that says 5.0 quality control,
12 talking about observing in 2016 that ZHP was not handling
13 chromatogram data and chromatogram testing properly.

14 I'm not saying quality oversight writ large and I'm
15 not asking questions or designating something about, later in
16 the report, 50 pages later, about Section 6.9, Customer
17 Complaints or some other issue -- Section 5.8, Microbial Labs,
18 sure, all of that is "quality," but I'm using Teva's own words
19 about this specific -- specific quality issue regarding ZHP's
20 chromatogram handling failures on a systematic basis.

21 SPECIAL MASTER VANASKIE: Yes, I believe that the dots
22 have been sufficiently connected and so would overrule the
23 objection and allow the testimony to be presented. That's the
24 testimony on page 135, line 15 to 136, line 6.

25 MS. LOCKARD: I understand your ruling, Your Honor. I

1 just -- if I could just complete for the record on this issue.

2 SPECIAL MASTER VANASKIE: Sure, absolutely.

3 MS. LOCKARD: Even plaintiffs' experts acknowledge
4 that you would not have seen this issue on a chromatogram. And
5 so the issues that are described in this report are not
6 connected to the issues in our lawsuit. There are just simply
7 too many dots.

8 The other thing I would point out for the record is
9 that this audit is heavily, heavily redacted because it relates
10 to other products, not valsartan. And the witness was being
11 asked questions about a document which is so heavily redacted,
12 you know, his answers are somewhat vague and speculative
13 because he doesn't have information because the document was
14 redacted. The document was redacted because in the discovery
15 orders, documents related to other products were not even
16 relevant to discovery and were not even part of the discovery
17 order.

18 So it is, in addition to being not relevant, it is
19 confusing, it is vague, and it is speculative because the
20 witness doesn't even have the information needed to answer the
21 questions. But I understand your ruling.

22 SPECIAL MASTER VANASKIE: Well, my ruling is not final
23 right now, it's just based upon what you had to say.

24 MR. STANOCH: Your Honor, there's nothing redacted on
25 the two pages, the two pages of this report that I ask and

1 designate Mr. Vadsola, absolutely nothing.

2 SPECIAL MASTER VANASKIE: But how is it connected to
3 the contamination of -- or alleged contamination of valsartan?

4 MR. STANOCH: Because the FDA said, Your Honor -- and
5 Teva's own review of this in 2018, 2019 is that ZHP, at this
6 very facility, right, that its quality control regarding
7 analytical testing and equipment as to chromatograms was
8 insufficient and that they should have looked deeper,
9 essentially, my words.

10 And this is saying that Teva, in August of 2016, in
11 unredacted pages -- by the way, they did the redactions, not
12 me, right? So I only have what they gave me and this is what
13 they gave me, which is prima facie relevant because they didn't
14 redact it, right? Rightly so.

15 That's saying, hey, look, we're seeing issues at this
16 facility from a quality control system standpoint that they're
17 not handling chromatograms correctly. And that's being -- I am
18 sorry, someone is trying to speak.

19 MR. NIGH: Yes, Your Honor, it's Daniel Nigh. I've
20 got to correct the record on one thing. Daniel Nigh for the
21 plaintiffs. I'm sorry I am not on video. I've got storm bands
22 from Helene going right on top of me. So that's happening
23 right now.

24 But one thing to correct the record, this same
25 argument came up for Torrent and I need to correct the record

1 again here because it's come up again, this idea that we have
2 no experts who speak to the chromatogram. This is taken
3 completely out of -- it's one expert where the plaintiffs say
4 you couldn't have discovered on the chromatograms, it's taken
5 out of context, it's Dr. Hecht.

6 We absolutely have an expert, Dr. Najafi. There are
7 numerous pages of an expert report, the defendants
8 cross-examined him, I don't know why they continue to omit
9 that. Of course we can connect the dots up through that
10 expert.

11 MR. STANOCH: That's right, Your Honor. I would add
12 that Dr. Najafi successfully survived the *Daubert* challenge and
13 our other GMP audit expert, Mr. Russ, who completely survived
14 the *Daubert* challenge as well, looks at all of these audits,
15 too, and opines -- and Judge Kugler said he can opine -- on
16 what these audits, including this one we're looking at in this
17 testimony, should have alerted Teva to do and ask more
18 questions and dive into these issues, and they didn't. So we
19 -- this idea that even we don't have expert evidence is a
20 complete fallacy.

21 MS. LOCKARD: Well, we disagree. This is getting far
22 afield. But Najafi did not testify that it would be
23 observable, nor did Russ, who was the expert against Teva.

24 But, Your Honor, what we I would suggest is that you
25 look at the transcript where Judge Bumb addressed this

1 specifically about connecting the dots and it can't just be
2 audits of the facility that do not directly relate to the
3 quality control issue that led to this problem.

4 SPECIAL MASTER VANASKIE: All right. I will -- you've
5 given me enough information to chew on that I'll reserve ruling
6 on the excerpt from page 135, line 15 to 136, line 6. I'll ask
7 that you provide me, Victoria, with the transcript of the
8 motion in limine hearing and rulings of Judge Bumb that concern
9 this particular excerpt. All right?

10 MS. LOCKARD: We'll be happy to do that. I think that
11 includes the issues on page 135, 137, 141, and 142? If
12 Mr. Stanoch agrees.

13 SPECIAL MASTER VANASKIE: That's from 137, line 10 to
14 140, line 4.

15 MS. LOCKARD: And also continuing on the next two
16 designations at page 142 and -- 141 and 142.

17 MR. STANOCH: That's probably right.

18 SPECIAL MASTER VANASKIE: And I had a note that the
19 question at page 139, lines 2 to 4 -- no, it's all right.

20 I think we go to page 140, line 4, correct? And then
21 also page 141, lines 23 to 142, line 11.

22 Do I have that right?

23 MS. LOCKARD: I show that we go from -- that there's a
24 dispute on page 137 that relates to this audit and there's a
25 dispute on page 141-23 to 142, line 11. So I think the second

1 one is correct, but I didn't see anything at page 140.

2 (Simultaneous speakers.)

3 MR. STANOCH: I think the judge had it right.

4 MS. LOCKARD: You're right, so 137 to 140, line 4,
5 correct. Okay.

6 SPECIAL MASTER VANASKIE: And so we'll reserve ruling
7 on that until I get the transcript from the in limine hearing.

8 MR. STANOCH: And, Your Honor, just for the record,
9 after you've had a chance to review, we would like an
10 opportunity again to argue or discuss it because --

11 SPECIAL MASTER VANASKIE: Correct. This is important.

12 MR. STANOCH: Yes, it's very important and we
13 disagree, obviously, with defendant's reading, which would
14 essentially gut all of -- if it's only an audit about something
15 ultra-specific as to NDMA, that's unduly prejudicial of a
16 reading, but we can readdress it later.

17 SPECIAL MASTER VANASKIE: All right.

18 MS. LOCKARD: So I think that takes us to page 142,
19 line 24.

20 SPECIAL MASTER VANASKIE: All right.

21 MS. LOCKARD: So this is a line of testimony
22 addressing another audit, and this relates to -- the audits
23 we've been talking about so far have been at the Chuannan
24 facility, which is the ZHP facility where Teva's valsartan API
25 was made.

1 We are now looking at audits related to the Zhengzhou
2 facility, which is a different facility and Teva's API was not
3 made there. And so none of these audits at this facility are
4 relevant because Teva's API was not made there and Teva was
5 auditing that facility for other purposes related to other
6 drugs.

7 Now, what you're going to hear from plaintiffs'
8 counsel is that --

9 MR. STANOCH: Can I say what I'm going to say, not
10 you, Ms. Lockard? I am sorry.

11 MS. LOCKARD: May I finish?

12 I believe based on our meet and confers, what I was
13 told was that plaintiffs believe it's relevant because that's
14 the facility where ZHP was making its finished dose valsartan.
15 And that may be true, I don't know.

16 But the audit that Teva was doing did not relate to
17 Teva's API valsartan and it didn't relate to ZHP's finished
18 dose. So it may be a facility where ZHP is making some
19 valsartan for itself, but it doesn't mean that it's relevant
20 and it doesn't mean that Teva's witness, Teva's audit witness,
21 should be testifying in court about this.

22 If they want to ask ZHP about the audits at that
23 facility related to ZHP's own finished dose, they have plenty
24 of other witnesses who can do that. It's not appropriate for
25 Teva's witness and it's not appropriate to talk about Teva's

1 audit of that facility because it doesn't relate to Teva's
2 drugs.

3 SPECIAL MASTER VANASKIE: All right. David?

4 MR. STANOCH: Thank you, Your Honor.

5 This is the facility, as Ms. Lockard correctly said,
6 is where ZHP made finished dose valsartan at issue in this
7 case. And it's relevant for us to present evidence that's
8 probative of any fact that's important for the jury to hear
9 that when Teva went into this facility, which is admittedly a
10 facility that made valsartan finished dose, and conducted an
11 audit, it specifically found that they were ignoring unknown
12 impurity peaks found in gas chromatography. Right?

13 That's the very issue, Your Honor has heard before
14 over and over, that is the issue that led Novartis to see
15 unknown peaks in chromatograms, right?

16 Ms. Lockard says this isn't about the valsartan API
17 that Teva was buying. It's certainly relevant as to the
18 facility that ZHP was making finished dose valsartan, which is
19 the subject of this trial, and I could certainly use evidence
20 of one party opponent that looked at the facility and said,
21 hey, you're ignoring unknown peaks, right, in your
22 chromatograms, to use that evidence in the trial against them,
23 including ZHP. That's fair game.

24 I'd also add, Your Honor, that although this
25 particular document, version of the audit report, and the scope

1 of products -- I know you don't have it, right, it's redacted.
2 Well, before today we went and found another version of this
3 which Teva produced with less redactions, and lo and behold,
4 the scope of the products include three different valsartan
5 products and says valsartan.

6 So to imply that this audit had nothing to do with
7 valsartan is completely wrong and we take issue, you know, with
8 redactions generally, but for purposes of this dispute we think
9 we've certainly shown the threshold of this is relevant,
10 relates to a relevant facility with a relevant issue that
11 relates -- right, the issue that would have been a problem with
12 valsartan.

13 MS. LOCKARD: Your Honor, they can certainly ask ZHP
14 and ZHP's witnesses about audits of the ZHP facility where
15 ZHP's valsartan was made, but it is a stretch to ask questions
16 and present testimony from Teva's auditor about an audit that
17 did not relate to Teva's products. And the reason that this
18 was redacted was because it did not relate to the Teva products
19 at issue in this case.

20 So --

21 SPECIAL MASTER VANASKIE: Well, it does seem to me
22 that it is relevant to the issues in the case. It may not be
23 relevant insofar as claims against Teva are concerned, but it's
24 certainly relevant insofar as the claims presented against ZHP.
25 It doesn't have to be a ZHP witness for the evidence to come

1 in.

2 So I will allow this testimony. I just want to make
3 clear what is covered by this ruling.

4 MR. STANOCH: Judge, I don't want to cut you off but
5 to help us on this administrative thing, maybe we could use the
6 row numbers on the spreadsheet. For example, I think it's rows
7 16 through 19, maybe that will save us some effort with page
8 and line quotes, but I'm happy to do whatever you and Ms.
9 Lockard --

10 SPECIAL MASTER VANASKIE: Yes, that's fine. That's
11 helpful, too.

12 I'm looking at row 16, that deals with simply an
13 answer: I don't know. So that's -- I think it picks up with
14 142, line 24.

15 MS. LOCKARD: That's what I show, Your Honor, which
16 should be row 17 --

17 SPECIAL MASTER VANASKIE: Row 17, row 18, row 19 --
18 17, 18 and 19, that's admissible.

19 MR. STANOCH: Understood.

20 SPECIAL MASTER VANASKIE: Is that clear enough for
21 everybody?

22 MS. LOCKARD: That's clear, Your Honor.

23 SPECIAL MASTER VANASKIE: All right.

24 MR. STANOCH: It is for the plaintiff. Just trying to
25 help us all try to move through it, Judge.

1 (Discussion held off the record.)

2 SPECIAL MASTER VANASKIE: And I think we're now at
3 row 20.

4 MR. STANOCH: I agree.

5 SPECIAL MASTER VANASKIE: And this picks up at
6 page 170. We're going to go until 11:00 and take a break then.

7 MS. LOCKARD: So on 170, there's no objection, but we
8 had proposed a counter because otherwise it's confusing, it's
9 misleading. They've gone from the prior designation talking
10 about one observation in the report to a new observation.

11 SPECIAL MASTER VANASKIE: And you want to put in the
12 169, line 23, to page 170, line 3?

13 MR. STANOCH: I agree, Judge.

14 SPECIAL MASTER VANASKIE: What's that?

15 MR. STANOCH: I agree, Judge and withdraw the
16 objection.

17 SPECIAL MASTER VANASKIE: Yes, that comes in.

18 So row 20, the page numbers and lines, that's
19 admissible, row 20.

20 MR. STANOCH: Understood.

21 SPECIAL MASTER VANASKIE: For both parties.

22 MR. STANOCH: Understood.

23 SPECIAL MASTER VANASKIE: I think that takes us to
24 row 21.

25 MR. STANOCH: Yes.

1 SPECIAL MASTER VANASKIE: And this is just an
2 objection to the plaintiffs' designation starting at page 172,
3 line 6.

4 MS. LOCKARD: So our objection on this -- so we have
5 been talking about observations that Teva made in the
6 testimony, and this next designation is highly confusing and
7 misleading because then it goes to, well, you understand that
8 it was made known in June of 2018 that ZHP had found unknown
9 peak in its valsartan API.

10 And so this is talking not about the audits that this
11 witness was there to testify about; this is talking about the
12 Novartis issue where Novartis identified an unknown peak and
13 raised that as a concern with ZHP.

14 And so this is taken totally out of context. It's
15 vague the way that it's asked. And there's no foundation for
16 it because we're switching gears from Teva's audits to suddenly
17 now we're asking about something that Novartis found. And it
18 will lead the jury to think or believe that Teva determined
19 this in its audits when it was actually another party.

20 MR. STANOCH: Judge, I'm allowed to shift gears in
21 questioning. I don't think that there's anything improper or
22 misleading of what happened here, especially when you look up
23 immediately prior on the page where we were having some
24 technical issues with this witness who I was deposing remotely
25 who was sitting in India.

1 A foundation, this is exactly what the question is,
2 I'm asking him: You understand when the unknown peak was found
3 purportedly in June 2018?

4 Yeah, that's correct. Right?

5 And then the ensuing questions go on about his
6 personal knowledge about it. I don't see -- if the issue is
7 foundation, I don't think that's appropriate because the
8 question itself is laying the foundation for his testimony and
9 I don't see how it's confusing.

10 All of these clips -- that's the whole point of
11 playing designations, there's nothing confusing about, quote,
12 switching gears from one topic to the other. If that was the
13 touch zone, then we're -- all of our clips could be
14 quote/unquote misleading, which I strongly disagree with.
15 Especially since they'll have their chance to put in
16 affirmative designations in some form in some way if there
17 really is an issue, but I just don't see it here, Judge.

18 MS. LOCKARD: Well, that's the problem with doing
19 deposition designations instead of calling live witnesses
20 because it doesn't allow the ability to build the foundation
21 and it makes some questions inappropriate and inadmissible.
22 And so this is one of those.

23 It is out of context. There is no foundation for it
24 even in the prior testimony. It just sort of throws this
25 question in and it is misleading to the jury. The question

1 itself is vague. We objected to the question at the time in
2 the deposition.

3 So we don't think it's appropriate. I mean, there
4 will be other witnesses to talk about the Novartis findings.

5 SPECIAL MASTER VANASKIE: You had a
6 counter-designation here, I believe. Do I have that right? At
7 172, line 17 to 174, line 11?

8 MS. LOCKARD: Right. That was a counter-designation
9 with the understanding that if this comes in, then we would
10 want the counter-designation to help explain this sort of
11 errant question.

12 SPECIAL MASTER VANASKIE: And what's your position,
13 David, on that counter-designation?

14 MR. STANOCH: It's inappropriate, not necessary, and
15 frankly, not responsive.

16 Your Honor, I don't understand what Ms. Lockard is
17 saying here about vagueness in that question: You understand
18 that it was made known in June 2018 that ZHP had found unknown
19 peak in its valsartan API, correct?

20 Yeah, that's correct.

21 That's it. That's all we're designating right there.

22 If I had him live, as Ms. Lockard mentions, right, I
23 could have certainly asked him questions about the audit
24 report, drop it on the table, and then turn around and ask that
25 next question and it wouldn't be sustained because it's

1 disjointed. I would be allowed to do that, number one. Right?

2 Number two, if you look at -- if Your Honor is
3 considering allowing in the completeness designation, right, I
4 ask a simple follow-up, right, about there was an unknown peak
5 in its chromatogram was the issue, right, and then look what he
6 does for over a page and a half.

7 I want you to take back to exactly what -- to
8 understand exactly what happened.

9 And he goes on and on and on, which honestly is very
10 different from a lot of this witness's other answers which were
11 much more succinct and forthright in answering questions.
12 Nothing he says there has anything to do, right, with his
13 understanding of, just to set the scene, that June 8, 2018, was
14 sort of this unknown peak that led to the recalls, right? And
15 then number two, the issue was an unknown peak in a
16 chromatogram, right?

17 All these things that go on and on and on about
18 investigations and other elements and other materials, I don't
19 see -- what does that have to do with the foundation that's
20 being laid here about his understanding of the issue that we're
21 here for?

22 MS. LOCKARD: The question asks for speculation
23 because it basically -- it doesn't say who found the unknown
24 peak. It suggests that it was Teva when it wasn't. And
25 they're suggesting that Teva found this unknown peak, they

1 don't say who. If the question had been worded, well, you
2 understand that Novartis discovered an unknown peak and made
3 ZHP aware, or something to that effect, that would not be an
4 objectionable question, but that's not what was asked.

5 MR. STANOCH: I don't say anything about Teva. It
6 says that ZHP had found an unknown peak in its valsartan API.
7 Nowhere do I say Teva found an unknown peak.

8 MS. LOCKARD: And, Your Honor, if this was a live
9 testimony, the witness would be able to explain and follow up
10 on the answer. Yes, an unknown peak was found. Let me tell
11 you what the significance of that is.

12 Ultimately, his answer, what he gets to in the answer
13 at page 174, line 6, is where he says that the unknown impurity
14 in the report, you can't conclude from this unknown impure --
15 excuse me -- you can't conclude that this peak relates to the
16 nitrosamine impurity, that's what he's saying.

17 MR. STANOCH: He didn't say the word "peak" once in
18 his two-page answer.

19 MS. LOCKARD: Well, he is an Indian witness with
20 English as his second language, but what he says is --

21 (Simultaneous speakers.)

22 MS. LOCKARD: Excuse me, I'm still speaking.

23 SPECIAL MASTER VANASKIE: Don't interrupt, David.

24 MR. STANOCH: I apologize, Judge.

25 MS. LOCKARD: He says: Any unknown impurity in any of

1 the report or in any of the chromatogram, it cannot conclude
2 that as on the nitrosamine impurity.

3 So I understand his -- it's a little bit broken in the
4 way that he answers it, but the message that he is conveying,
5 which I think the jury will understand, is that you cannot
6 conclude from the report of the unknown peak, from the report,
7 the Novartis report, that it's the nitrosamine impurity.

8 So you're -- so Mr. Stanoch is saying, yeah, but, you
9 know, there was an unknown peak that was discovered. And
10 Mr. Vadsola is saying, well, yes, but let me tell you why
11 that's not significant because you can't conclude that that
12 unknown peak was the nitrosamine impurity.

13 So he's entitled to explain his answer, whether it's
14 live or if it's in the deposition.

15 SPECIAL MASTER VANASKIE: All right. So we're dealing
16 with row 22 of the spreadsheet. I will allow both the
17 designation and the counter-designation. So the testimony from
18 page 172, line 12 through 174 -- I'm sorry, page 172, line 12
19 to line 13; and 172, line 17 through 174, line 11 will come in.

20 And let's take a 15-minute break now. Thank you.

21 MS. LOCKARD: Thanks, Judge.

22 (Brief recess taken from 10:56 a.m. to 11:14 a.m.)

23 SPECIAL MASTER VANASKIE: All right. Do we have
24 everybody back?

25 MR. STANOCH: I'm ready for plaintiffs, Your Honor.

1 MS. LOCKARD: I'm ready for Teva.

2 SPECIAL MASTER VANASKIE: All right. I'm just trying
3 to see where we're at now.

4 What row are we on? Are we on row 24?

5 MS. LOCKARD: 23.

6 MR. STANOCH: I agree.

7 SPECIAL MASTER VANASKIE: Row 23?

8 MR. STANOCH: Yes.

9 SPECIAL MASTER VANASKIE: And that's testimony at page
10 176, line 4 to 177, line 5. There's an objection as to 177,
11 lines 3 to 5.

12 MS. LOCKARD: So, Your Honor, I don't --

13 SPECIAL MASTER VANASKIE: Go ahead.

14 MS. LOCKARD: So, you know, we went back and we looked
15 at this and I believe we would withdraw our objection to this
16 section and as well as to rows 24 and 25 if we're able to play
17 our affirmative designation which is listed in row 7.

18 And so the portion that we objected to essentially was
19 Mr. Stanoch asking about Teva -- about what Teva missed in its
20 audit.

21 SPECIAL MASTER VANASKIE: Right.

22 MS. LOCKARD: And so in looking at that, you know, we
23 do believe that the question is vague and misleading, but I
24 tend to think Your Honor is probably going to rule against us
25 on that.

1 But I think we resolve our objection if we're able to
2 then give Mr. Vadsola's answer at 196-14, the question; and his
3 answer at 196-19, where the question is asked again and he
4 says: I don't agree with that because I want to give you some
5 explanation on this part. And then he provides his example for
6 why he does not agree that Teva missed the issue.

7 SPECIAL MASTER VANASKIE: All right. David?

8 MR. STANOCH: Your Honor, I'm having a little trouble
9 following. It sounds like we're not going to have an issue or
10 objection from 176-4 forward for the next few designations but
11 that Ms. Lockard would condition that on her counter of 196-14,
12 the question, and then the ensuing answer.

13 SPECIAL MASTER VANASKIE: Right.

14 MR. STANOCH: I don't agree with that, Your Honor. I
15 think, you know, the designations and objections prior to that
16 at 176, 177, 179, 185, I think they're appropriate questions
17 and appropriate answers.

18 And then to jump down more than ten pages where
19 Mr. Vadsola goes on again with a very long statement that talks
20 about regulatory agencies, which talks about chemists, which
21 talks about the DMF process for multiple pages, I would have
22 objections to this, and I do, if they're making an affirmative
23 designation which we can address; but I don't see how any of
24 this 20 pages later is an appropriate completeness objection.

25 He talks about preapproval inspection, he talks about

1 what ZHP submitted, he talks about what documents went to a
2 regulatory agency. I can go on and on and on on this counter
3 that they have here around 196 through 199 for three pages of
4 him just talking -- not responsive, I might add -- that's just
5 littered with speculation and things outside of his foundation
6 and so forth. And it certainly has nothing to do for
7 completeness 20 pages earlier.

8 MS. LOCKARD: So it is a completeness designation
9 because it pertains to his answer to the same question that we
10 objected to. The question we objected to was: But Teva missed
11 this issue about the genotoxic impurity in the valsartan API,
12 didn't it?

13 And he says: I defer here because I don't know where
14 they write this observation.

15 And in our completeness designation, which even though
16 it's pages later, Mr. Stanoch asks the same question where he
17 says: Right. And Teva missed this NDMA nitrosamine
18 contamination issue in the valsartan API, didn't it?

19 So he asked the question a second time, and the
20 witness said: I don't agree that because I want to give you
21 some explanation. So then he explains why he doesn't agree.

22 And Mr. Stanoch wants to cut off and stop with the
23 first question and answer where Mr. Vadsola says, you know, I
24 don't know, I defer.

25 And then Mr. Stanoch went on pages later and came back

1 to the exact same question and then gave an answer which
2 Mr. Stanoch and plaintiffs don't like, but it is the complete
3 answer.

4 And if Mr. Vadsola were on the stand testifying live
5 and Mr. Stanoch questioned him as he did on lines 177, and if
6 he tried to impeach him with page 177, Mr. Vadsola would say
7 yes, but Mr. Stanoch, remember, later in the deposition you
8 asked me the same question, and I told you I don't agree and
9 gave his explanation.

10 So I think in the designation, the same rules apply,
11 so he should be able to give that affirmative -- or excuse me,
12 that counter.

13 MR. STANOCH: If I withdraw 177-8 through 177-10,
14 which Ms. Lockard says is the Q and A that preceded her counter
15 20 pages later, then the issue goes away. I'll do that.

16 MS. LOCKARD: So you withdraw 177-8 to 10 and the
17 answer to that question?

18 MR. STANOCH: 177-3 is the question.

19 SPECIAL MASTER VANASKIE: 177, line 3 is the question.

20 MS. LOCKARD: Okay. 177, line 3 to 177-5.

21 MR. STANOCH: Is the question.

22 MS. LOCKARD: And that's what's gone?

23 MR. STANOCH: And then the answer is 177-8 through 10.
24 That was the one -- all right. So if we remove that, then I'm
25 hearing there's no completeness issue, because this is the one

1 question and answer Ms. Lockard identified as justifying her
2 completeness designation from 20 pages later.

3 SPECIAL MASTER VANASKIE: And you agree, Victoria?

4 MR. STANOCH: Again, I'm not saying she cannot
5 affirmatively try to put that in, we'll fight about that later;
6 but for purposes of this, I'll do that.

7 MS. LOCKARD: Hold on. I'm looking at this.

8 Yes, I will agree with that.

9 SPECIAL MASTER VANASKIE: All right. So we will not
10 be playing page 176, lines 3 through 5 and 176, lines 8 through
11 10.

12 MR. STANOCH: I'm sorry, Judge, it's 177.

13 SPECIAL MASTER VANASKIE: 177. The page numbers are
14 at the bottom of the page.

15 MR. STANOCH: I know, they're hard to see.

16 SPECIAL MASTER VANASKIE: And I see 176 when I'm
17 looking at the -- so 177, you're absolutely right, lines 3
18 through 5 and 177, lines 8 through 10 will not be played, nor
19 will we play 196, lines 14 through 16 and 196, line 19 through
20 page 199, line 8. Correct?

21 MR. STANOCH: That's what I have.

22 MS. LOCKARD: That's right.

23 SPECIAL MASTER VANASKIE: Okay. So now are we on
24 row 27?

25 MS. LOCKARD: We're on row 26.

1 SPECIAL MASTER VANASKIE: Row 26. 185 -- let me get
2 there -- line 19 to 186-23.

3 MS. LOCKARD: So we did not have an objection, we
4 withdrew it.

5 SPECIAL MASTER VANASKIE: Right.

6 MS. LOCKARD: But there was an affirmative that
7 plaintiff objected to.

8 SPECIAL MASTER VANASKIE: And that's at 184, line 14
9 through 185, line 18.

10 MS. LOCKARD: Correct. And our counter is the
11 question that's being asked is: As hub manager, did you tell
12 the auditors that went to ZHP that they should look at the
13 chromatograms?

14 And he says: I don't remember -- he gives his answer.

15 SPECIAL MASTER VANASKIE: Right.

16 MS. LOCKARD: But the counter I think is necessary for
17 completeness, because in that question Mr. Stanoch had asked:
18 Did you give them any direction whatsoever as to what they
19 should look at?

20 And then the answer by Mr. Vadsola is explaining, I
21 don't tell them what to look at. You know, in a routine GMP --
22 I mean, in a routine audit, they go in and they decide what to
23 look at.

24 So without that counter, it's misleading because it
25 makes it seem as if Vadsola is instructing them what to look

1 at.

2 SPECIAL MASTER VANASKIE: David?

3 MR. STANOCH: I don't think the extra background is
4 necessary for completeness. It's simply asking, you know, did
5 he tell something specific to the auditors he oversees when
6 they went on this May 2018 audit of ZHP, and he says no.

7 SPECIAL MASTER VANASKIE: Yes, I think the designation
8 by Teva is appropriate for completeness purposes and would
9 allow the testimony from line 14 on page 184 to line 18 on
10 page 185. So all of row 26 would come in.

11 MR. STANOCH: Understood, Judge.

12 SPECIAL MASTER VANASKIE: All right. Now we're to
13 row 27, part of which has been resolved, I think.

14 MR. STANOCH: I thought it was resolved, but I'm not
15 sure.

16 SPECIAL MASTER VANASKIE: Yes, I'm just looking at
17 page 201 to see if that's all resolved.

18 MS. LOCKARD: So this is a slightly different issue.
19 So we had an objection as to lines 21 to 23.

20 SPECIAL MASTER VANASKIE: Yes.

21 MS. LOCKARD: And so this is -- the objection here is
22 in addition to the others, but there's a lack of personal
23 knowledge problem with this and relevance, because he's asking
24 about a different customer of ZHP who found the contamination
25 on its first look at that API. And the witness says he doesn't

1 know, he doesn't know if Novartis found this on its first look.

2 MR. STANOCH: Your Honor, that's the question. I'm
3 probing his personal knowledge; he gives me his answer based on
4 personal knowledge.

5 I don't see what the issue is. He's not speculating.
6 I'm not -- no one is putting any words in his mouth. I said,
7 did you know X? He says, no, I can't comment, I don't know.

8 MS. LOCKARD: But under the rules, the witness has to
9 have personal knowledge, and he doesn't. And if he doesn't
10 have personal knowledge, then it's irrelevant and it's a waste
11 of time just to ask the witness, you know, and he says I don't
12 know.

13 MR. STANOCH: Now I'm hearing 403, which is not any of
14 the many objections that were listed. They said vague; I don't
15 think it's vague, I'm asking a very specific question. They
16 said misstates evidence; I haven't heard a thing about that.
17 And calls for speculation; I'm asking him what he knows. And
18 it's probative of what the Teva audit hub manager knew or
19 didn't. It's not -- now I'm hearing it's a waste of time. If
20 he was on the stand, I would simply ask him, did you know X,
21 I'm not sure, and we move on.

22 MS. LOCKARD: We talked about this objection in the
23 meet-and-confer conversation, but he's a Teva audit hub
24 manager. That doesn't mean that he knows what another company
25 customer of ZHP found, if it was their first look, second or

1 third.

2 So you're asking him a question he doesn't have an
3 answer to, he doesn't know the answer to, and it implies that
4 he should know the answer to, but he shouldn't.

5 MR. STANOCH: Your Honor, that's a jury question.
6 Should the audit hub manager who oversaw Teva's for-cause audit
7 after the recalls know about what the issue was at ZHP? They
8 sent people in to audit ZHP again to say, oh, my gosh, what
9 happened. We're going to deal with that in a few rows, right?
10 And he's like, I don't know.

11 This isn't this sort of, oh, did you know at that
12 time? Even as of now and everything that was happening, did
13 you know that? No. This guy has no idea of what the sequence
14 of events was for the nitrosamine contamination that led to
15 worldwide recalls? I still don't even know what the objection
16 is on this, Your Honor.

17 MS. LOCKARD: This does not -- this is not a witness
18 saying he has no idea about the sequence of events. This is
19 Mr. Stanoch asking an audit manager at Teva, well, didn't
20 Novartis find this on their first look? On their first look.
21 He doesn't know this.

22 It's not appropriate, he doesn't have the foundation,
23 and he doesn't have the personal knowledge to know if Novartis
24 found this on his first look.

25 So they can get that in by other witnesses perhaps who

1 have the personal knowledge and the foundation, but this
2 witness, just to ask him, well, hey, Novartis found this on the
3 first look, didn't it?

4 And the witness says, I don't know.

5 I mean, that is exactly what the personal knowledge
6 objection goes to.

7 MR. STANOCH: Well, they didn't state personal
8 knowledge in their objection, so, again, it's sort of a moving
9 target. And I'm not trying to hold Ms. Lockard to her
10 spreadsheet. I'm flexible on that. But --

11 MS. LOCKARD: Well, we did meet and confer.

12 MR. STANOCH: I certainly tried to over the last two
13 weekends. But I'm just saying, Your Honor, I ask him a
14 question, does he know something. Part of the Teva team
15 investigating the root cause analysis of what happened with
16 this, right, getting -- what happened, ZHP, come up, blah,
17 blah, blah. He says, oh, I don't know if it was a different
18 customer or not. That -- it's probative. I don't hear how
19 it's prejudicial or not.

20 He doesn't know the story, fine; but a jury can say,
21 well, maybe the audit hub manager who was in charge of helping
22 to put together the for-cause audit and root cause analysis
23 should have known that, should have been like, hey, how did
24 this happen, and maybe he should have some recollection.

25 MS. LOCKARD: So I think it's prejudicial because they

1 can't sneak in this first look language. That's the point.
2 He -- everybody knows that Novartis found this. Nobody knows
3 if it was a first look or what.

4 And this is not the witness who's in charge of the
5 investigation. His limited role is in doing audits of the
6 company. So he's not privy to all of the full investigation at
7 Teva. He wasn't a 30(b)(6) on that. He was a personal
8 knowledge witness. He's not a 30(b)(6); he's a personal
9 knowledge witness. And he doesn't know about all of the
10 workings of the Novartis notification and what they found or
11 how quickly they found it.

12 I mean, he goes on in the deposition to say -- he's
13 asked, well, do you understand the customer was Novartis, and
14 he says no. I know the company Novartis, but I cannot say that
15 what they've done with nitrosamine impurity in valsartan API.
16 I mean, that just wasn't his role at Teva.

17 MR. STANOCH: Your Honor --

18 SPECIAL MASTER VANASKIE: Go ahead, Mr. Stanoch.

19 MR. STANOCH: I'm sorry, Judge, I hate to belabor it
20 for two lines.

21 Two pages later I ask: I'm just asking, you know,
22 that it was a different customer that found the nitrosamine
23 impurity in the ZHP valsartan API, right?

24 Answer: Maybe. Yes, to say that's another customer,
25 I would say yes, that's true, because the same thing is

1 published in newspaper and journal.

2 So, yes, fair enough to say that another customer
3 found. That's true.

4 MS. LOCKARD: Right. And we objected to that
5 testimony as well because he's saying, well, that's what I saw
6 in the newspaper. I mean, it's just not an appropriate -- this
7 guy does not have the personal knowledge on the Novartis notice
8 issue. There's lots of other witnesses to testify about that.

9 MR. STANOCH: Again, Your Honor, I could put in
10 witnesses I ask, percipient witnesses investigating the root
11 cause. This idea that, oh, somebody else can come in and say
12 that.

13 I can establish and show the jury what people on the
14 ground at the time involved in the investigation say they knew
15 or didn't know.

16 SPECIAL MASTER VANASKIE: But he didn't --

17 MS. LOCKARD: He wasn't --

18 (Simultaneous speakers.)

19 SPECIAL MASTER VANASKIE: -- the testimony, he doesn't
20 acknowledge that it was Novartis that found the contamination.

21 MS. LOCKARD: Right, because he doesn't know. He
22 wasn't in charge of the root cause investigation. We put up
23 30(b)(6) witnesses on that. Dan Barreto testified about that.
24 We had other witnesses to talk about the investigation. This
25 witness was there to talk about his personal knowledge of the

1 audit that Teva did at the ZHP Chuannan facility. He's not
2 there to talk about the overall investigation or what Novartis
3 did or knew or how quickly they found it.

4 MR. STANOCH: What I'm hearing, Judge, is any time we
5 ask a witness did you know X and they say "I don't know," that
6 that's -- somehow that's prima facie inadmissible. I disagree
7 that that's the rule.

8 MS. LOCKARD: That is not the position we are taking.
9 If it's a witness who is testifying about his personal
10 knowledge of a subject or is a 30(b)(6) who's designated on a
11 subject and they say they don't know, then yes, there's no
12 objection to that.

13 But you can't just bring in a witness from Teva who's
14 there to testify about what personal knowledge he has involving
15 one aspect of the case and then start asking him questions
16 about, you know, other facts that he has no involvement, no
17 personal experience or knowledge of. That's why there's a rule
18 on it.

19 MR. STANOCH: How would I know that, Judge, without
20 asking him this question?

21 SPECIAL MASTER VANASKIE: No, I think the question is
22 all right, but the problem I'm having with it, David, is that
23 the question is: But, in fact, a different customer of ZHP
24 found the contamination on its first look at the API, right?

25 And his answer is: I don't know. I cannot comment

1 about other customers, what they find.

2 And so the question includes an assertion that doesn't
3 get confirmed by the witness.

4 MR. STANOCH: So that's information that he says he
5 doesn't possess, that's what's been established. I don't
6 understand how that's prejudicial or confusing or misleading
7 when I'm trying to establish foundation and knowledge of what
8 this witness knows or doesn't, then when he says he doesn't,
9 how that then is irrelevant or not probative.

10 MS. LOCKARD: So Rule 602 says: A witness may testify
11 to a matter only if evidence is introduced sufficient to
12 support a finding that the witness has personal knowledge of
13 the matter.

14 So, yes, you have to ask the question to establish the
15 foundation that this witness has personal knowledge. If he
16 does have personal knowledge, then you can go on to ask the
17 questions about that issue.

18 Here, Mr. Stanoch was trying to establish the
19 foundation, and he could not because the witness confirmed he
20 did not have personal knowledge. So under Rule 602, it should
21 not come in to admissible testimony before the jury.

22 SPECIAL MASTER VANASKIE: I will sustain the
23 objection.

24 MS. LOCKARD: Okay. Thank you, Judge.

25 I think the next one is the same --

1 SPECIAL MASTER VANASKIE: Is this one row 27, this
2 one?

3 MR. STANOCH: Yes, and 28.

4 MS. LOCKARD: Right, 27 and 28.

5 SPECIAL MASTER VANASKIE: All right. 27 and 28, I
6 just sustained the objection.

7 We're now to row 29. I think this is out as well.

8 MS. LOCKARD: Right. I think that's the same issue.

9 MR. STANOCH: For the record, I'll note we think it's
10 permissible to ask a witness what's within their personal
11 knowledge, and if they say they don't know or it's not, that's
12 permissible, but I understand your ruling.

13 Certainly when he's acknowledging what he's read about
14 what happened, which is his personal knowledge, is saying yes.

15 MS. LOCKARD: That he read it in the newspaper? I
16 mean --

17 MR. STANOCH: So now that I ask him what his personal
18 knowledge is, and he says, yes, I do have knowledge and states
19 the basis for that knowledge, now that's out too?

20 MS. LOCKARD: I think we're just getting afield on
21 this, but, yes, we would object if the witness is testifying
22 based on what he read in the newspaper because that would also
23 be hearsay, but I don't think we need to go down that track.

24 SPECIAL MASTER VANASKIE: I -- yes. And let me just
25 explain too, my rulings here are influenced by my understanding

1 that there's going to be other evidence that comes in on this
2 point. It's just that this witness wouldn't be the appropriate
3 witness.

4 MR. STANOCH: Understood, Your Honor.

5 SPECIAL MASTER VANASKIE: So does that take us to
6 row 30 now?

7 MR. STANOCH: Yes.

8 MS. LOCKARD: Yes.

9 SPECIAL MASTER VANASKIE: Page 210.

10 MS. LOCKARD: This was a plaintiffs' objection to our
11 counter.

12 MR. STANOCH: Right. The only issue is whether Teva's
13 counter of 211-11 to 212-2 come in.

14 SPECIAL MASTER VANASKIE: Okay.

15 MS. LOCKARD: And our counter -- initially plaintiff
16 had designated that portion of the testimony in their
17 affirmatives, they revised it to take it out, and so we added
18 it to our counter.

19 SPECIAL MASTER VANASKIE: And I will allow the
20 counter.

21 MR. STANOCH: Understood.

22 SPECIAL MASTER VANASKIE: All right. Now row 31.

23 MS. LOCKARD: So we had an objection to this based on
24 foundation and Rule 402 and 403. And, I mean, this is
25 questioning about from an OTBN being skipped and not reviewed.

1 It sort of lacks foundation here as well.

2 SPECIAL MASTER VANASKIE: What's this all about,
3 David?

4 MR. STANOCH: This is just audit practices about what
5 is or is not put down. You know what, Judge, I'll withdraw
6 this designation.

7 SPECIAL MASTER VANASKIE: Okay, it's withdrawn.

8 MR. STANOCH: 216-5 through 8 and the answer --

9 SPECIAL MASTER VANASKIE: 5 through 8 and the answer
10 at 11-12.

11 MR. STANOCH: Agreed.

12 SPECIAL MASTER VANASKIE: All right. That takes us to
13 row 32.

14 MR. STANOCH: Yes, sir.

15 SPECIAL MASTER VANASKIE: This is at page 218, lines
16 14 to 219, line 11. And it seems to me the objection here is
17 to the counter that starts at 219, line 12 to line 16, and 219,
18 line 19 to 219, line 22.

19 But there is an objection to the testimony at 216,
20 lines 5 through 8. Let me take a look at that.

21 MR. STANOCH: Oh, I just withdrew that, Your Honor.

22 SPECIAL MASTER VANASKIE: Okay.

23 MR. STANOCH: 216-5 through 8 withdrawn.

24 SPECIAL MASTER VANASKIE: Yes.

25 MR. STANOCH: So I think the only issue is row 32,

1 it's the completeness issue.

2 SPECIAL MASTER VANASKIE: Right.

3 MR. STANOCH: And I think to move it along, I would be
4 inclined to just withdraw our objection on completeness, but I
5 want to add after -- their completeness objection ends at
6 219-22, I want to go to the next question at 219-24 to 220-13
7 just to finish that block of questioning.

8 SPECIAL MASTER VANASKIE: So you would add in the
9 question at 219 -- 220, line 22 and the answer --

10 MS. LOCKARD: So -- I am sorry, but I think you do
11 have that already designated, Mr. Stanoch, but it's not just on
12 that spreadsheet because we did not dispute that designation.

13 MR. STANOCH: Oh, that's why -- oh, look at that.
14 Well, you know what, in that case, I'll withdraw the objection
15 to the counters.

16 MS. LOCKARD: Yeah, so you've got all that next page
17 and half designated.

18 MR. STANOCH: So, Judge, I am sorry. We withdraw it.

19 SPECIAL MASTER VANASKIE: Okay, good. As to row 32 of
20 this spreadsheet, all of that testimony designated there will
21 come in.

22 MR. STANOCH: Yes, sir. You see, Your Honor, we took
23 out things that were not disputed, so that's why it was
24 confusing me. Sorry.

25 SPECIAL MASTER VANASKIE: Gotcha. So we are at row 33

1 now, I take it?

2 MR. STANOCH: I believe so. Correct.

3 SPECIAL MASTER VANASKIE: This is a designation at
4 page 221, line 23 to 222, line 8.

5 MS. LOCKARD: Yeah. And our objection to this, Your
6 Honor, is there's -- I mean, there's really no question. He's
7 just telling the witness to read the paragraphs, and then
8 Mr. Stanoch is saying, you know, read these paragraphs, they're
9 similar to what we saw before, just take a moment and scan
10 these couple of paragraphs, let me know when you're done; and
11 the witness says okay.

12 So I don't know why we need that.

13 SPECIAL MASTER VANASKIE: Yes, I had trouble with
14 that, David.

15 MR. STANOCH: Because that was sort of the leadup then
16 to the next designation where we talk about what we talked
17 about earlier. Right? I was orienting the witness and trying
18 to shortcut the deposition, you know, at midnight, say, right,
19 this is talking about X, we saw some of that before, do you see
20 that? He says yes. And I say right. And then I jumped to --
21 we had talked earlier about the fact that there was a finding,
22 blah, blah, blah, and he says, yes, yes, yes.

23 MS. LOCKARD: I mean, I don't have a real problem with
24 that. If you think you need it to set up the next question,
25 then I'll withdraw that objection.

1 SPECIAL MASTER VANASKIE: All right. So I'm confused
2 by row 34. Page 222, line 23 to 225 --

3 MR. STANOCH: I think the only issue is Ms. Lockard
4 wants to add just a single question and answer at the end of
5 this back and forth --

6 (Simultaneous speakers.)

7 SPECIAL MASTER VANASKIE: Yes, I see that now.

8 MR. STANOCH: I think that's the only issue.
9 Honestly, if she wants it in, you know what? I'll agree to the
10 completeness.

11 SPECIAL MASTER VANASKIE: All right. So for row 33,
12 it all comes in.

13 MR. STANOCH: Yes, sir.

14 SPECIAL MASTER VANASKIE: And for row 34, it all comes
15 in.

16 MR. STANOCH: Yes, sir.

17 SPECIAL MASTER VANASKIE: Okay. So that is all in.
18 That takes us to row 35. We're really moving now.

19 MR. STANOCH: We're trying, Judge.

20 (Laughter.)

21 MS. LOCKARD: So the issue here is that this line of
22 questions relating to this observation discusses a different
23 drug, irbesartan, not valsartan at issue in this case. And so
24 it's not relevant. And other drugs were not even part of the
25 discovery order, and so we would ask that the testimony related

1 to observations that pertain to other drugs be excluded.

2 MR. STANOCH: Your Honor, the discovery order was not
3 so limited. In fact, it allowed for discovery regarding other
4 nitrosamine issues or testing issues that may -- I don't have
5 the wording in front of me, but when Magistrate Judge Schneider
6 entered it years ago, other testing issues that could have
7 related to those that were at issue with valsartan. Right?
8 This is no different than the ZHP email that we all know of
9 talking about irbesartan and then crossing it over connecting
10 dots to valsartan. This is the same type of issue that here
11 we --

12 SPECIAL MASTER VANASKIE: Yes.

13 MR. STANOCH: Right?

14 SPECIAL MASTER VANASKIE: I will overrule the
15 objection.

16 MS. LOCKARD: Okay. I understand your ruling. This,
17 by the way, for the record, is nothing like the infamous ZHP
18 email.

19 (Laughter.)

20 MS. LOCKARD: But I understand it's an observation in
21 the report where we looked at valsartan. We think irbesartan
22 issues should be out, but I understand the Court's ruling, so
23 we can move on.

24 SPECIAL MASTER VANASKIE: Okay. Thank you.

25 MR. STANOCH: I think the same rationale would apply

1 for the next few, but I'm not trying to jump the gun.

2 SPECIAL MASTER VANASKIE: No, I think so, too. I'm
3 just trying to...

4 MS. LOCKARD: Yeah, I believe our objection was on the
5 same grounds.

6 MR. STANOCH: Yes.

7 SPECIAL MASTER VANASKIE: So where does that take us
8 to now, what row?

9 MS. LOCKARD: To row 37.

10 SPECIAL MASTER VANASKIE: Okay.

11 MS. LOCKARD: Page 229.

12 SPECIAL MASTER VANASKIE: 229, line 21.

13 MS. LOCKARD: So we did have an objection based on it
14 being a non-valsartan product, but I think that is covered.
15 However, the lines at 230-19 to 231-3 are cumulative of prior
16 testimony where this was discussed.

17 SPECIAL MASTER VANASKIE: David?

18 MR. STANOCH: I don't see how it's cumulative,
19 especially since if we were talking about completeness, this
20 really eases the flow of this whole particular Q and A talking
21 about specific observations by Teva auditors and specific
22 issues in their audit report.

23 SPECIAL MASTER VANASKIE: Yes, I'll overrule the
24 objection.

25 Are we up to row 39 now?

1 MR. STANOCH: I think so.

2 MS. LOCKARD: Yes. Wait. 38.

3 SPECIAL MASTER VANASKIE: 38. Okay. Sorry. 231-6 to
4 231-22.

5 MR. STANOCH: Your Honor, I'd say this is the same
6 type of issue.

7 MS. LOCKARD: I think it is. I think our objection
8 was as to the Irbesartan being a different drug.

9 SPECIAL MASTER VANASKIE: Okay. I'll overrule the
10 objection.

11 MS. LOCKARD: So line 30, row 39.

12 My only objection was as to the answer, so I think
13 that's covered. I did not have an objection as to the
14 remainder of that designation starting with the questions.

15 SPECIAL MASTER VANASKIE: So the question starts at
16 line 16.

17 MR. STANOCH: I think what she's saying, Judge, is
18 even though we designated about a page, the very first line,
19 232-14 is actually the answer to the prior designation. So I
20 think your overruling of the objection to the question would
21 apply to the only objection here, which is the answer.

22 SPECIAL MASTER VANASKIE: Okay.

23 MS. LOCKARD: Right. So it all comes in.

24 SPECIAL MASTER VANASKIE: It comes in.

25 MS. LOCKARD: Based on your ruling.

1 SPECIAL MASTER VANASKIE: Yes. Are we up to row 40
2 now or still on to row 39 actually?

3 MS. LOCKARD: Row 40.

4 MR. STANOCH: I agree.

5 MS. LOCKARD: So our objection to this, and I think
6 this has permeated through some of the other witnesses as well,
7 so it's a lack-of-personal-knowledge objection primarily.
8 Mr. Stanoch is asking this witness about ZHP's responses to the
9 FDA in their Form 83, which Mr. Vadsola had nothing to do with
10 ZHP and their responses to the FDA. And so Mr. Stanoch is
11 basically just walking through ZHP response to FDA and asking
12 Mr. Vadsola about what's on the paper. And so I don't think
13 it's appropriate for this witness to be testifying about that.
14 That lacks personal knowledge on the part of this audit
15 witness.

16 MR. STANOCH: Your Honor, may I?

17 SPECIAL MASTER VANASKIE: David?

18 MR. STANOCH: Your Honor, that's not what's happening
19 here. The document -- and I know you probably don't have it in
20 front of you --

21 SPECIAL MASTER VANASKIE: I don't.

22 MR. STANOCH: The document is a Teva document which is
23 a Teva audit report of the ZHP Chuannan site about the ZHP
24 issues, and it's the Teva's auditors, including Mr. Pan Lin,
25 who we'll get to today or tomorrow, right, talking about what

1 their views -- Teva's thoughts on ZHP's responses to the FDA
2 Form 483. This isn't Mr. Vadsola speculating. This is him,
3 the audit hub manager, testifying about a Teva audit report of
4 ZHP, written by Teva auditors, about the explanations that ZHP
5 is trying to give the FDA, which it's sharing with Teva.
6 That's highly probative and relevant. It's certainly not
7 misleading. It's certainly within the personal knowledge of
8 this audit hub manager overseeing this very audit that the
9 audit report is about. And, in fact, the answers to the
10 questions, he's very straightforward, he agrees what the
11 document is, and he answers what he remembers.

12 SPECIAL MASTER VANASKIE: The one that I had concern
13 on was the last question in this exchange that appears at
14 line 8 of page 236: Prior to the FDA's Form 483, was Teva
15 itself aware that ZHP did not always conduct a formal risk
16 assessment for critical changes, et cetera? And the answer is:
17 I don't know. Why shouldn't I strike that last question and
18 answer?

19 MR. STANOCH: I would say, Judge, that this is a
20 little different than the issue we addressed before about
21 Mr. Vadsola's knowledge because here, the audit and the CGMP
22 issues, right, are talking about the failures that -- that the
23 FDA said and that Teva is talking about at ZHP, right, and this
24 is the audit hub manager, and he's saying I don't know about
25 what Teva did or did not know about whether ZHP did formal risk

1 assessments. I think it's probative for a jury to hear that
2 the person who is in charge of the auditors who are supposed to
3 go to ZHP and see if they're doing things like formal risk
4 assessments knows or remembers one way or the other whether
5 that was happening.

6 MS. LOCKARD: Well, we objected to this in part
7 because he's not a 30(b)(6) witness and you're not asking him
8 if he was aware of this. You're asking him if Teva is and
9 you're asking him to speak on behalf of the company when he's
10 not a 30(b)(6). So that's why we made an objection to this
11 part.

12 You know, as to the full sequence of that designation,
13 Mr. Vadsola was not on the document that's being asked about.
14 Mr. Pan Lin was on that document, he was asked about it, and I
15 think Mr. Lin would have personal knowledge to discuss the
16 document but Mr. Vadsola was not on this document.

17 MR. STANOCH: I would just say it was in his custodial
18 file.

19 SPECIAL MASTER VANASKIE: I will sustain the objection
20 in view of the fact that Vadsola was not a 30(b)(6) witness and
21 you're asking him to testify as to what Teva itself was aware
22 of.

23 MR. STANOCH: Understood, Your Honor.

24 SPECIAL MASTER VANASKIE: So I think that takes care
25 of rows 40 and 41.

1 MR. STANOCH: I agree.

2 SPECIAL MASTER VANASKIE: So row 42.

3 MR. STANOCH: I would just volunteer, Your Honor, that
4 that's slightly different because here he's saying from my
5 knowledge, I don't think so.

6 SPECIAL MASTER VANASKIE: Yes. And we have a
7 counter-designation at 237-15 to 238-10.

8 MS. LOCKARD: And we would maintain that the same
9 rationale for excluding the prior designation applies here.

10 SPECIAL MASTER VANASKIE: They did qualify it --

11 MS. LOCKARD: True.

12 SPECIAL MASTER VANASKIE: -- as per my knowledge, so
13 I'll allow that. And I was inclined to allow the
14 counter-designation.

15 MS. LOCKARD: Okay. We can live with that.

16 SPECIAL MASTER VANASKIE: All right. So they'll come
17 in. That brings us to row 43.

18 MR. STANOCH: 43 I think was just the answer, so I
19 think it just continues.

20 SPECIAL MASTER VANASKIE: Yes.

21 MR. STANOCH: Sorry.

22 SPECIAL MASTER VANASKIE: It is.

23 MR. STANOCH: And then I think row 44, beginning on
24 page 238-18. I guess we needed the question. It looks like we
25 cut that off, I'll be honest.

1 SPECIAL MASTER VANASKIE: Yes.

2 MR. STANOCH: Oh, that's probably because she didn't
3 dispute it. I think, Judge, what I'm seeing is I believe
4 Ms. Lockard only has on objection to 242-17 through 23, and
5 then the ensuing answer to that.

6 SPECIAL MASTER VANASKIE: Oh, okay.

7 MS. LOCKARD: Yeah.

8 MR. STANOCH: And I'll even short circuit it, Your
9 Honor. Based on the last couple that we did, I think your same
10 rationale would probably apply here, in terms of what he knew.

11 SPECIAL MASTER VANASKIE: Right.

12 MR. STANOCH: In fairness.

13 MS. LOCKARD: So 242-17 to 23 is out, right? And the
14 answer to the question in the next row, 45?

15 MR. STANOCH: Yes.

16 SPECIAL MASTER VANASKIE: Correct, they're out.

17 MR. STANOCH: I then go to row 46, beginning at
18 page 243-18. I would just say this one's a little different,
19 maybe I got this one right, Judge, that I qualify it to his
20 knowledge.

21 SPECIAL MASTER VANASKIE: Yes.

22 MS. LOCKARD: We maintain the objection, but I won't
23 argue it.

24 SPECIAL MASTER VANASKIE: Yes, I'll overrule the
25 objection and allow in 243-18 to 23.

1 So does this take us to row 47?

2 MR. STANOCH: Yes, Your Honor.

3 I think the objection is only to the question at 245,
4 7 through 14.

5 I think here I'm just asking an audit hub manager what
6 his personal expectation would be of his auditors and he
7 answers it.

8 SPECIAL MASTER VANASKIE: Yes. The objection is
9 overruled. That comes in.

10 MR. STANOCH: I think that applies to the next one as
11 well because it picks up -- the next clip picks up the answer
12 to that question --

13 SPECIAL MASTER VANASKIE: Yes.

14 MR. STANOCH: And then it's another question,
15 personally.

16 MS. LOCKARD: Hold on a sec.

17 MR. STANOCH: Sure. Sorry.

18 MS. LOCKARD: Okay.

19 SPECIAL MASTER VANASKIE: I think that comes in as
20 well.

21 MR. STANOCH: Okay.

22 SPECIAL MASTER VANASKIE: That gets us to row 49.

23 MR. STANOCH: Agreed. The objection is speculation,
24 and I think 402 and 407. Again, Ms. Lockard can speak first,
25 if she'd like. I'll just preview my views, Judge. On these

1 ensuing questions -- well, number one, they're asking about a
2 for-cause audit that Teva conducted of ZHP in the fall of 2018,
3 right? So the recalls happened. This is the for-cause audit.
4 Teva is going in to see what happened with the actual NDMA
5 issues. Right? So, number one, there's no speculation in this
6 because he was the audit hub manager at the time overseeing the
7 auditors who were going in and working on the audit report
8 itself.

9 The 407 objection, which you'll see here on line, I
10 believe -- I don't want to put words in her mouth, but I
11 believe Teva's position is that because this audit took place
12 after the recalls, right, a month or so after, that it's a
13 subsequent remedial measure, and we strongly disagree with
14 that. This isn't some issue of doing something after an
15 accident so the accident doesn't happen again. This is
16 literally the same instance, right, the actual recall on the
17 NDMA issues to figure out what was the cause and identifying
18 what the cause was. There's literally no subsequent remedial
19 measure being taken, let alone by Teva. Right? This is them
20 saying what the heck happened here, and that doesn't fall
21 within the ambit of 407. And there's other issues, but I can
22 respond after you hear more from Ms. Lockard.

23 SPECIAL MASTER VANASKIE: Victoria?

24 MS. LOCKARD: Right. Your Honor, we have a strenuous
25 objection to the audit from September 2018, the for-cause audit

1 of ZHP. We are not saying that Teva's internal investigation
2 into this issue itself is subsequent remedial measures. We are
3 saying that this audit where Teva went into ZHP to do a
4 for-cause audit to correct measures, they issued
5 recommendations and corrections to ZHP to ensure that this did
6 not happen again. It is exactly like going in after an
7 accident and making corrective measures. It's exactly like,
8 throughout the law, if an employer sanctions or reprimands or
9 terminates an employee after an event because of something that
10 was subject to a lawsuit or an injury. It's exactly like that.
11 It is ZHP going in, essentially reprimanding their supplier for
12 what was done which caused or contributed to this exact
13 incident.

14 So it is squarely within 407 and subsequent remedial
15 measures. So it's the exact same policy reason that applies.
16 That's why we have subsequent remedial measures, so that people
17 in Teva's shoes will not be fearful of going in and doing a
18 thorough, comprehensive for-cause audit to identify all the
19 mistakes and require and recommend corrections.

20 So we think it is directly analogous to the case law
21 that says that subsequent remedial measures are excluded.

22 We also discussed this similarly with some emails
23 related to our witness Mr. Karlsson who we argued that this
24 sort of, you know, Monday-morning questioning of what ZHP did
25 and how they should be corrected going forward, and Judge Bumb

1 excluded those Karlsson emails on the same ground.

2 So we feel very strongly that this for-cause audit and
3 request for corrections is squarely within a subsequent
4 remedial measures objection.

5 MR. STANOCH: Your Honor, I can respond unless you
6 want to ask any questions or make a statement.

7 SPECIAL MASTER VANASKIE: No, go ahead and respond.

8 MR. STANOCH: Thank you, Judge.

9 Number one is I'm not arguing anything about
10 Mr. Karlsson. We'll address his designations once I ever get
11 the final counters and objections back from Ms. Lockard.

12 Number two is, a root-cause analysis, right, by
13 definition, is backward-looking. We're looking at what were
14 the issues in the past that was the reason for this
15 contamination. There's nothing about actions being taken in
16 the future, let alone what Teva is taking. If Ms. Lockard's
17 rationale were correct, the FDA Form 483 and warning letter to
18 ZHP would be inadmissible because it was issued in the fall of
19 2018 as well, which says, hey, ZHP, this is what you did wrong,
20 this is why your product was adulterated. You didn't do this,
21 you didn't do that, you didn't do that. This is the same type
22 of thing. There's no subsequent remedial measure actually
23 being taken here. This is looking back at the conditions in
24 the past that led to the contamination.

25 And furthermore, it also goes to our case against Teva

1 in terms of its quality oversight, that they had a
2 responsibility as the finished dose manufacturer buying this
3 API, right, to -- all that time they should have been looking
4 at these things, right, and whether or not Teva believed they
5 were -- ZHP was complying with GMP and whether they were
6 acceptable or unacceptable. And we'll get into later, you'll
7 see emails from Teva where the auditors, the actual people on
8 the ground who did this audit, said because of these CGMP
9 failures at ZHP which caused this contamination and recalls,
10 ZHP, it's an unacceptable supplier. Right? That's highly
11 probative and pertinent and relevant for sure and it has
12 nothing to do about, oh, in the future, years from now, what we
13 should do so it doesn't happen again, that's a completely
14 different issue.

15 SPECIAL MASTER VANASKIE: Yes, go ahead, Victoria.

16 MS. LOCKARD: We have objected to those emails and
17 you'll hear that when we get to Mr. Vadsola.

18 SPECIAL MASTER VANASKIE: Right.

19 MS. LOCKARD: The regulatory issue -- the argument
20 that Mr. Stanoch makes about 483s and FDA activity, that is
21 expressly excluded in the case law that addresses the
22 subsequent remedial measures rule, Rule 407. The case law says
23 that does not apply to regulatory reports and FDA evaluations
24 post-fact, so it's not analogous at all.

25 The issue here is exactly what subsequent remedial

1 measures, the policy and the rule, is for. It's what it
2 applies to. It is Teva going in, essentially, and questioning
3 and reprimanding retrospectively their supplier, and that's
4 exactly what subsequent remedial measures is for. And
5 plaintiff can come out and they can bring up our risk documents
6 and they could say, well, Teva should have found this earlier
7 and Teva's earlier audits were ineffective and incomplete, they
8 can make that. But they can't take a subsequent audit to argue
9 liability, which is exactly what they're trying to say.
10 They're saying, okay, so you looked at this after the fact and
11 you said, well, ZHP, they should have done all of this stuff
12 and they didn't, they got to do it going forward. Teva, we
13 should have seen this before or, you know, we erred, and
14 they're evaluating that in an audit report and that is exactly
15 a subsequent remedial measure. So it is inadmissible.

16 SPECIAL MASTER VANASKIE: Well, respectfully, I
17 disagree. It's an investigation into what happened and I think
18 the results of that investigation, you can call it an audit,
19 are admissible or probative. What they did as a result of the
20 investigative report may be a remedial measure, but that's not
21 the issue here.

22 So to that extent, I overrule the objections.

23 MS. LOCKARD: Okay. I understand. And just for the
24 record, we are not saying that Teva's investigation of this
25 issue was a subsequent remedial measure. We're saying going in

1 and doing a for-cause audit and the documents associated with
2 that for-cause audit is the remedial measure. That's the
3 activity that's being undertaken. That's the corrected
4 activity in and of itself is just performing this for-cause
5 audit. They would not have done that but for the issue. But I
6 understand Your Honor's ruling.

7 SPECIAL MASTER VANASKIE: Okay. Thank you.

8 Where does that leave us now?

9 MR. STANOCH: Your Honor -- and Ms. Lockard, I'm not
10 trying to cut her off -- frankly, I think Your Honor's ruling
11 just now would apply straight through to the end because I
12 think that's the primary issue. And I'm not trying to cut off
13 Ms. Lockard, and she can certainly disagree, but I think that
14 was sort of the overarching issue because I think the remaining
15 designations are really about this for-cause audit Teva did in
16 the fall and sort of the finalization of it internally at Teva.

17 SPECIAL MASTER VANASKIE: Well, I will say this, and
18 then I want to hear from Victoria, but I had preliminarily
19 determined that the objections from here, where we are now,
20 through the end of the deposition should be overruled. But
21 there's a couple of limited exceptions. Let me get to the
22 exceptions and then, Victoria, we'll hear from you.

23 I have in my notes: Overrule except at page 270 lines
24 8 to 11. So let me look and see what that is.

25 And the question at 8 to 11 is: Why is Mr. Barreto

1 asking David Hatt and Linda Hoover to take the first shot at
2 fixing the contents of the report? The answer was: I don't
3 know. But I don't think that's appropriate at all. I think it
4 did call for speculation.

5 MR. STANOCH: I won't belabor it, Your Honor, but if I
6 may for 30 seconds?

7 SPECIAL MASTER VANASKIE: Go ahead.

8 MR. STANOCH: You'll recall from the questioning
9 immediately prior and after this that Mr. Vadsola is a
10 percipient witness on all the emails and had conversations with
11 all these people about the preparation of the report and we
12 asked, oh, do these people usually get involved? No. Right?
13 And so the question is, okay, you, as the audit hub manager,
14 who's, you know, supposed to be working with the auditors to
15 oversee that, you know, why do you think that these other two
16 people are getting involved? He doesn't know. He said he had
17 conversations with Mr. Barreto before about the preparation of
18 this. I think it's fair to sort of ask him what he recalls, if
19 anything, and counsel's objection prompting him, frankly, with
20 an answer, if you know. I'm allowed to ask him, okay, this is
21 happening right now, you're preparing these documents, do you
22 know why? He could have said, yes, because X, because Dan
23 Barreto told me this on the phone. He could have said, no, he
24 doesn't remember, he doesn't know. I think that's fair given
25 all the context that's happening of these conversations and

1 emails that are happening.

2 MS. LOCKARD: Well, we did not object to the lines
3 prior to that about who was there and why they were there. I
4 think he is entitled to answer that. But we do object and
5 maintain our objection to this section that you've flagged,
6 Judge Vanaskie, for the reasons that you've said. It is
7 speculation. Mr. Barreto will be testifying and he was asked
8 about this and he can be asked about it again.

9 SPECIAL MASTER VANASKIE: Yes. No, I will sustain the
10 objection with respect to the matters at page 270, lines 8 to
11 11.

12 Another one I have --

13 MR. STANOCH: And the answer at 14. I'm just stating
14 that for the record.

15 SPECIAL MASTER VANASKIE: And the answer at 14,
16 correct.

17 MR. STANOCH: Yes, sir. Thank you.

18 SPECIAL MASTER VANASKIE: And then I have sustained
19 the objection at page 254, lines 4 to 7 and page 254, line 10
20 to 21, which is the answer.

21 MR. STANOCH: I'm not going to argue that, Judge. I
22 agree that page 254, 4 through 7, question, and answer at 254,
23 10 through 14 are out.

24 SPECIAL MASTER VANASKIE: All right. Now, Victoria, I
25 said that I had gone through the transcript, I made preliminary

1 determinations to overrule the objections through the balance
2 of the transcript. Maybe I should give you the opportunity to
3 go over that to see if there's anything in particular you want
4 to argue, but I think it was basically the same subsequent
5 remedial measure issue.

6 MS. LOCKARD: By and large, I think that's correct.
7 There may be one or two other small things, and maybe we can
8 look at those over lunch or I can kind of confirm if there's
9 anything else. But I agree, the vast majority of the remainder
10 would be covered by your prior rulings.

11 SPECIAL MASTER VANASKIE: Okay. So why don't we break
12 for lunch. You can go over these other designations to which
13 objections were asserted and which I've preliminarily
14 overruled, or I'll say I have, in fact, overruled, and you can
15 argue for reconsideration. But we'll break now for lunch and
16 we'll resume at 1:30, if that's all right.

17 MR. STANOCH: Your Honor, just, much like Ms. Lockard
18 had a medical appointment to go to on Tuesday, I need to slip
19 away for 20 minutes around 1:45 to 2:15. So I'm happy to come
20 back at 1:30 and address sort of this issue, but if it's
21 possible, maybe for everyone's benefit if we can focus -- shift
22 to maybe a ZHP or Torrent person and then I'll be back no later
23 than 2:20.

24 SPECIAL MASTER VANASKIE: We certainly can switch to
25 the ZHP persons because I'm ready for them if you all are ready

1 for --

2 MR. SLATER: Yes, we are, Judge.

3 MS. LOCKARD: And the other thing I would add, Judge
4 Vanaskie, is given your rulings today on Mr. Vadsola, I think
5 we may be able to eliminate a number of them from Pan Lin
6 because some of the objections were the same with respect to
7 which audits were in and out.

8 SPECIAL MASTER VANASKIE: Okay.

9 MS. LOCKARD: So we can work on that this afternoon
10 and maybe reduce those so that we could get to Pan Lin maybe
11 tomorrow.

12 SPECIAL MASTER VANASKIE: Okay.

13 MR. STANOCH: I agree with that.

14 SPECIAL MASTER VANASKIE: Let's break now until 1:30.
15 David, if you need to go for your medical appointment,
16 go.

17 We'll pick up with the ZHP witnesses. I don't think
18 they're going to take very long, but you never know. And then
19 we'll come back to -- that will give you a little extra time,
20 Victoria, to see if there's anything in this balance of
21 Mr. Vadsola's testimony that you want to seek reconsideration
22 of.

23 MS. LOCKARD: Sounds good.

24 SPECIAL MASTER VANASKIE: Okay. Thank you all. See
25 you at 1:30.

1 (Luncheon recess taken from 12:21 p.m. to 1:33 p.m.)

2 SPECIAL MASTER VANASKIE: We're going to resume now
3 with designations from ZHP witnesses. I'd like to start with
4 John Iozzia, I-O-Z-Z-I-A, if I'm pronouncing that right.

5 MS. ROSE: Yes.

6 SPECIAL MASTER VANASKIE: If I'm pronouncing that
7 incorrectly, correct me.

8 MS. ROSE: It's John Iozzia, Your Honor.

9 SPECIAL MASTER VANASKIE: Iozzia, okay. All right.
10 And the first -- if we can, I'll just jump right in, but I did
11 want to ask Mr. Slater a question.

12 I received last night a motion, I guess it's a motion
13 to strike objections with respect to witnesses. I'm getting
14 that wrong. A motion to strike objections to wholesaler
15 defendants asking questions of witnesses. That's close to it,
16 anyway.

17 And how soon can you have a response to that motion?

18 MR. SLATER: I'll have to ask the people that are
19 working on that. I can't imagine it would take very long. I
20 would think by the end of next week.

21 SPECIAL MASTER VANASKIE: Okay. Find out for me. I
22 might want to accelerate that even more.

23 MR. SLATER: Okay. And for everybody on the Zoom, if
24 you are involved in that, please email me on our side and tell
25 me what you guys need so I can let the judge know.

1 MS. LOCKARD: I'll just speak up for a moment. I
2 think this relates -- it's crossfire involving our witness,
3 Teva's witness, but this is in the losartan depositions that
4 are ongoing.

5 SPECIAL MASTER VANASKIE: Yes, that's right, so that
6 doesn't have time emergency.

7 MS. LOCKARD: Yes. I mean, I'm not saying it's not
8 important, but I just --

9 SPECIAL MASTER VANASKIE: I didn't read it carefully.

10 MS. LOCKARD: I want you to know that it does not
11 relate to the TPP trial.

12 SPECIAL MASTER VANASKIE: Okay. So don't worry about
13 getting me a response quickly on that. We'll set a deadline
14 for that.

15 MS. LOCKARD: Maybe I shouldn't have spoken up.

16 SPECIAL MASTER VANASKIE: No, I'm glad you did.

17 All right. So we're dealing with John Iozzia, the
18 deposition designations. The first one concerns a
19 counter-designation, the first excerpt at issue, and that's the
20 counter-designation at page 76, line 9 to page 77, line 7.

21 MR. SLATER: Yeah. We've been emailing during the
22 first part of the hearing. I was hoping that maybe we worked
23 it out. I don't know if Nina thinks we worked it out or not.

24 MS. ROSE: I think we're very, very close. I think
25 we're down to maybe one line as to whether -- or two lines as

1 to whether they should come in. So I believe we've narrowed it
2 just to lines 76 through -- 15 through 16.

3 And do you want to just talk the judge through what we
4 agreed to and then just discuss those two lines?

5 MR. SLATER: Sure. Would that help, Judge?

6 SPECIAL MASTER VANASKIE: Yes, absolutely.

7 MR. SLATER: Okay. So what I proposed is to allow
8 them the following counters: 75-15 to 22. I realize it wasn't
9 listed on the chart, but I was trying to address their concern
10 and give them more than what they asked for on certain things
11 and less on others. So 75-15 to 22 would be a counter.

12 SPECIAL MASTER VANASKIE: Hold on for one second,
13 please, for me, while I find that transcript.

14 MR. SLATER: Yes, no problem, Judge.

15 SPECIAL MASTER VANASKIE: Okay. Now I have the
16 transcript. And what page and line?

17 MR. SLATER: Okay, Judge. So what we have agreed to
18 is that they can have a counter at 75-15 to 22. Also, which I
19 realized was not on the spreadsheet, but as I was saying, we
20 offered that to try to give them what they were essentially
21 trying to attain. So we've agreed to give 75-15 to 22 as a
22 counter. Also, 76-9 to 15 through the word "experience," not
23 including "the years of FDA track record," and then to pick up
24 again on 76, line 20 with "and you know" and take that to the
25 end. So the only dispute is whether on line 15 and 16 "the

1 years of FDA track record" would come in.

2 MS. ROSE: Your Honor, can I be heard?

3 MR. SLATER: I think I got that right. Correct? I
4 think I got it right, Nina, right?

5 MS. ROSE: Generally. So I just wanted to clarify.

6 So ZHP did not ask for the counter at 15 through 22.
7 We have no issue with it coming in. But I just want to clarify
8 that they've designating a different section that really isn't
9 our counter, which is fine, fine by me.

10 But on page 76, the question starting at 9 and going
11 through to page 77-7, that's a question and a complete answer.
12 I think our issue with how plaintiffs are trying to cut up this
13 answer is they're trying to take out relevant parts of the
14 answer. We were willing to compromise and take out lines 17
15 through 20 to the word "recall" because plaintiffs had stated
16 that they had a concern that that statement indicated that
17 Mr. Iozzia was talking about the track record of the company
18 prior to the valsartan at issue being manufactured in 2011,
19 which is when Mr. Iozzia had joined the company. So we were
20 willing to take that out. We don't think that's the case, but
21 we were willing to compromise with plaintiffs.

22 But now with this issue of trying to cut up the answer
23 even further to take out the years of FDA track record, there's
24 just no basis for that. The FDA track record with respect to
25 valsartan is an issue in the case that's going to be talked

1 about by both sides. We have experts. They have experts. I
2 don't think there's any argument that that's not allowed.
3 That's part of the regulatory history of this case.

4 SPECIAL MASTER VANASKIE: Adam?

5 MR. SLATER: Sure. First of all, I had thought we had
6 worked something out on part of this. So 75-15 to 22, I'm not
7 going to designate that. I was offering to give that to the
8 defendant because they said they wanted a more fulsome answer.
9 If you don't want to include that as a counter, Nina, please
10 drop it. I'm not going to include it for me. That was for
11 your benefit. I thought I was giving you a great deal of
12 testimony to try to address your concern about defining
13 quality. So if you don't want that, don't take it. It's there
14 for the taking, but it's your counter. If you don't want it,
15 we're not going to designate it. That's 75-15 to 22.

16 Now, getting to the years of FDA track record, that is
17 so imprecise and so general that -- what does that mean? Years
18 of FDA track record across the entire company having nothing to
19 do with -- look, counsel is nodding her head. I think we're
20 going to do better if we just focus this.

21 The witness doesn't say anything about valsartan. He
22 says that he -- the company's quality goes to their years of an
23 FDA track record. So there was an MIL that was granted in the
24 defendant's favor that we couldn't get into parts of
25 inspections and regulatory background that wasn't specifically

1 linked to the valsartan or the facilities where the valsartan
2 was manufactured.

3 This testimony is completely untethered to anything
4 other than a general statement of we had a great FDA track
5 record, which we dispute. We have issues with some of the
6 inspections that were done over the years leading up to 2018.
7 They were criticized. They got dinged by the FDA. We weren't
8 planning to put any of that in. So it shouldn't go in because
9 it has nothing to do with anything. It's just a wide-open,
10 untethered phrase that the witness threw in about this great
11 track record, and it shouldn't come in.

12 That's my argument. And I'm going to try to keep my
13 arguments brief and maybe counsel can too because I think we'll
14 get through this a lot quicker if we both agree to do that.

15 MS. ROSE: I'm happy to, Adam. I would just like to
16 respond.

17 SPECIAL MASTER VANASKIE: Nina.

18 MS. ROSE: Thank you very much. I will keep it brief.

19 So I think this issue of FDA track record, as Your
20 Honor has recognized in ruling on the Teva designations, there
21 were objections by Teva on talking about certain inspections
22 and things that have happened with the FDA. And Your Honor
23 said that those can generally come in.

24 So this -- the fact that there was a very broad
25 question asked about what does quality mean, and he answered

1 that quality has to do with the years of -- has to do with the
2 track record with the FDA, that is an issue that's definitely
3 coming in by both sides, what happened with the FDA. I don't
4 think plaintiffs can object that it's too broad of a statement
5 or not and precise enough of a statement. If counsel had
6 wanted to at the time, could have asked the question, when you
7 say FDA track record, what are you referring to? And he
8 didn't. So I -- it's just not fair to cut up a witness's
9 answer. I do not think that FDA track record would have been
10 stricken if this witness were testifying live.

11 MR. SLATER: It's fine if it comes in. I just want
12 counsel to know what's good for the goose is good for the
13 gander. I keep hearing that. So if ZHP wants to put in a
14 witness saying that they had this phenomenal FDA track record,
15 we're going to assume -- and counsel just said that was a Teva
16 issue, not a ZHP issue, we'll be ready to cross their witnesses
17 with all of the bad inspection findings over the years, because
18 it can't go only one way. I'm willing to keep that out and not
19 get into that area, and I thought the judge ordered us not to.
20 But if ZHP is willing to open the floodgates over this one
21 phrase, I just want to make it clear for the record, we are
22 going to bring whatever we have to cross-examine their
23 witnesses.

24 MS. ROSE: Your Honor, in light of what Adam has said,
25 I think this goes further. I don't think it -- I do not think

1 that this opens the door by saying in response to what does
2 quality mean, talking about the FDA track record with respect
3 to valsartan, I don't think that that opens the door to them
4 talking about unrelated FDA inspections or FDA issues related
5 to other products and other facilities. I think that's unfair.
6 So I think this opens up a whole bigger issue if plaintiffs are
7 going to say that this opens the door. And maybe this is
8 something that Judge Bumb has to clarify a motion in limine on.

9 MR. SLATER: Judge, let's be very clear. This
10 question is based on a language in a marketing document from
11 the company that has nothing to do with valsartan. It's
12 generally about the -- not nothing to do with it. It's not
13 limited to valsartan. It's about the company in general. And
14 I asked about a phrase on page 74-22 where it says "quality is
15 our lifeline." And I asked, what does that mean as used in
16 that brochure. He couldn't answer the question limited to
17 that, so he wanted to give a broad answer. So to say that this
18 is limited to valsartan, it's not limited to valsartan. That's
19 just not true.

20 SPECIAL MASTER VANASKIE: Let me ask a question of
21 clarification.

22 Nina, you're willing to strike the answer at lines 17
23 to 20, "You know, I joined the company because they had an
24 exceptional track record up until the point of the recall"?

25 MS. ROSE: Yes, Your Honor. As a compromise, I'm

1 willing to take that out to avoid any suggestion by plaintiffs
2 that we are opening up issues prior to the valsartan track
3 record.

4 SPECIAL MASTER VANASKIE: But you want to keep in the
5 years of the FDA track record?

6 MS. ROSE: I don't see that there's a reason to take
7 it out. I'm very concerned by Mr. Slater using this to reargue
8 motions in limine. And if there's -- I think that we would
9 need to have Judge Bumb clarify her motion in limine in ruling.
10 I would not want this one phrase to be, as Mr. Slater
11 suggested, opening up the whole motion in limine on unrelated
12 regulatory documents.

13 So I'm not really sure what to say because I think
14 that there's no reason to exclude that phrase, but at the same
15 time I would not want to take a position that there is some
16 chance that -- if there's some chance that Judge Bumb's motion
17 in limine ruling is going to be overruled. So I think that's
18 something we would have to clarify with Judge Bumb before we
19 could go into this.

20 MS. LOCKARD: Your Honor, if I may speak up because I
21 heard something I didn't want to hear. But, you know, we're
22 not in this, I don't want to interject, but to the extent that
23 there's an argument that this opens the door to getting into
24 Teva's regulatory history, we're going to have to get involved
25 in this. So --

1 MR. SLATER: I didn't say anything about Teva.

2 MS. LOCKARD: You did. You said --

3 MR. SLATER: I didn't know anything -- what I said is
4 ZHP. I said if ZHP wants to say they have this great track
5 record with the FDA in general across the board and have a
6 witness say that, then I think at that point we're allowed to
7 put in evidence that refutes it.

8 I can't believe we're fighting over these six words
9 this much, but I guess that's what we're going to do today. I
10 mean, it's just -- it's such an easy call here, but okay.

11 MS. LOCKARD: I just didn't want to be accused of
12 sitting silent. If your position is that this is not opening
13 the door to anything to do with Teva, then I'll step back down.

14 MR. SLATER: I don't want to start to be the expert on
15 Teva right now. You guys have been arguing for days. You know
16 what the MIL ruling was. There's a transcript. I'm just
17 limiting it to these six words. I can't believe we're fighting
18 over this this much. It's unbelievable.

19 MR. RAE: Your Honor, Jacob Rae on behalf of Torrent.
20 Can I be heard briefly?

21 SPECIAL MASTER VANASKIE: Go ahead.

22 MR. RAE: I don't want to get into this specific issue
23 here either, much like Ms. Lockard, but I do have concerns
24 about the fact that Mr. Slater I think just took a position on
25 the scope of Judge Bumb's MIL ruling with respect to

1 defendants' MIL 2 where -- that is consistent with arguments
2 that we have been making that plaintiffs have been disagreeing
3 with both in front of Your Honor and in our meet-and-confers as
4 to the fact that as I think Mr. Slater acknowledged right now,
5 EIR reports and other materials at facilities that are not
6 related to valsartan have been excluded from this case. And I
7 just want to make it clear that, I hear Mr. Slater saying that
8 he agrees with that position, but kind of the counsel who are
9 handling Torrent witnesses and I think the counsel who are
10 handling Teva witnesses appear to disagree with that position.
11 And I want to make sure that we all are on the same page there.

12 MR. SLATER: Look, I know what the judge ruled. If
13 you want to say the years of FDA track record, it's not limited
14 to anything, it's across the board, so I think it would open
15 the door. That's it. That's my position.

16 MR. NIGH: And just to be clear -- it's Daniel Nigh
17 now -- with Torrent. It came up before with Teva. Judge, to
18 say there was -- it's obviously clarified that if there's
19 evidence of a systemic failure, that could also be admissible.
20 Judge Bumb was very clear in her wording when she said that.
21 So to take one thing out of context and say this is the full
22 ruling, that actually doesn't apply to this argument that's
23 happening right now. But they are different issues.

24 MS. ROSE: Your Honor, may I be heard? I think I can
25 short-cut this.

1 SPECIAL MASTER VANASKIE: Yes.

2 MS. ROSE: Thank you. I am willing to take out the
3 years of FDA track record. I strongly and ZHP strongly
4 disagrees that a witness, when asked a question when responding
5 to that question about quality with respect to valsartan,
6 cannot mention the FDA track record.

7 But there's so many people jumping in now, I think we
8 can short-cut this, I'm happy to take out those five words
9 because I really don't think in the context of this deposition
10 it's going to affect ZHP's position.

11 SPECIAL MASTER VANASKIE: All right. Those six words
12 are stricken.

13 MR. SLATER: Thank you. I'll send you flowers later,
14 Nina.

15 (Laughter.)

16 SPECIAL MASTER VANASKIE: All right. The next area I
17 have in dispute starts on page 146 of Mr. Iozzia's deposition.
18 This is at line 16 to 23 with the answer to follow at 147-2 to
19 147-4.

20 Do you want to say anything more on this, Adam?

21 MR. SLATER: I would just say that this is the head of
22 marketing for them in the United States for their API, and I
23 asked -- this is talking about the -- I believe it's talking
24 about the DMF or the change control -- let me just see.

25 It's the change notification when they notified their

1 customers that there was no change to the impurity profile, no
2 adverse change. That's what everybody was told who was buying
3 this stuff.

4 And I asked him: If there was an adverse change,
5 would you expect that you would then be selling the API to
6 customers with an adverse change to the impurity profile?

7 And he very logically said what any normal, rationale
8 human being on the planet earth would say is: We would not be
9 selling a product that had an issue with the process.

10 I don't understand how they say that this is something
11 that's outside of the scope. This goes directly to the core
12 issue of the value. The defense is arguing, well, the fact
13 that there was an impurity didn't change the value. Their head
14 of marketing in the United States is saying we wouldn't be
15 selling it if there was an adverse change.

16 I don't see how it could be more central. And he's
17 not speculating; this is what he does for a living. He runs
18 the department.

19 MS. ROSE: Your Honor, may I be heard?

20 SPECIAL MASTER VANASKIE: Yes.

21 MS. ROSE: Thank you.

22 So I think this issue is Adam is talking about a
23 marketing executive who made very clear that he's not a
24 scientist and he did -- the term "impurity profile" and the
25 specific meaning of that term is not within his area of

1 expertise. It's not something that he can talk about. But
2 that's not even the issue.

3 The issue here is that this is an incomplete
4 hypothetical, where it's discussing, one, a change to the
5 impurity profile, what that means and what specifically, like,
6 the impurity profile is. And then the other thing is that it
7 doesn't indicate whether the -- ZHP in this hypothetical knew
8 about an -- that there was an adverse change or not. So if --

9 MR. SLATER: If I asked all those questions, it would
10 be compound.

11 SPECIAL MASTER VANASKIE: All right. Please don't
12 interrupt.

13 MR. SLATER: I am sorry, Judge, I won't do that again.
14 I apologize.

15 SPECIAL MASTER VANASKIE: Here's how we're going to
16 handle this. I'll hear from each side once and then I'm going
17 to rule. And, you know, we're not going to go on interminably
18 back and forth.

19 So, Nina, please complete your statement and we'll
20 move on.

21 MS. ROSE: I think I had completed my statement, Your
22 Honor.

23 SPECIAL MASTER VANASKIE: I'm going to allow this
24 exchange to be played for the jury. I think the hypothetical
25 is sufficiently complete for this witness to provide the answer

1 that he did provide. And I think that's it for Mr. Iozzia.

2 MR. SLATER: That's it, Judge.

3 MS. ROSE: Yes, Judge.

4 SPECIAL MASTER VANASKIE: I'd like to next go to Jie
5 Wang.

6 And this is from his deposition on May 18, 2021. The
7 first area of dispute begins on page 42, line 9. The question
8 is: Are you aware that one of the problems that the FDA had
9 with your company's operations after it was determined that
10 NDMA was in your company's valsartan was an inadequate customer
11 complaint handling system? Were you aware of that?

12 What's the basis for the objection, Nina?

13 MS. ROSE: Your Honor, the basis for the objection is
14 that this witness is not a regulatory witness, and as
15 designated, it suggests that the witness should have known
16 about this communication with the FDA and was somehow -- the
17 company was -- acted wrongly. And because this witness's
18 answer was that was not specifically aware of the FDA's
19 communication, I think that is prejudicial and it's suggestive
20 of some sort of negligence on the part of the party that
21 doesn't exist because this is not a company witness who
22 interacts with the FDA.

23 SPECIAL MASTER VANASKIE: All right.

24 Adam?

25 MR. SLATER: Thank you, Judge.

1 His designation was on ZHP's oral and written
2 communications with their customers. The backdrop to this is
3 questioning that permeates this deposition where he's taken
4 through a series of complaints from customers going back to
5 2014 who are buying valsartan API from ZHP, and every one of
6 them was saying, we're seeing all these unidentified peaks on
7 the gas chromatography and we don't know what this is and we
8 don't know what these impurities are and you need to tell us.

9 And our position is, based on the evidence, that ZHP
10 was putting them off and giving them inadequate and false
11 explanations. And all the while, ZHP knew what was going on
12 and they knew that there were problems with this impurity
13 profile but weren't telling anybody.

14 So that was the back and forth that he's asked about
15 throughout the deposition.

16 The FDA looked at the -- how they handled these
17 complaints about these unidentified peaks begins in 2014 and
18 said that they had an inadequate customer complaint system and
19 they didn't adequately address these complaints.

20 So it's literally his topic, and I'm asking him, are
21 you aware that what your company did in communicating with your
22 customers was found by the FDA to be inadequate? Because he's
23 explaining what they did and didn't do, so it's exactly what
24 the topic is.

25 The fact that he's not designated on FDA

1 communications doesn't mean that I can't ask him about the fact
2 that his topic the FDA spoke to because it speaks directly to
3 what his topic is. He is the only witness that was the
4 appropriate person to ask about that, both of those issues.
5 That's why we got into it with him, because he was designated
6 on the topic of those communications.

7 So the idea that this is beyond his designation, it's
8 unreasonable.

9 And you'll see on the next designation, the European
10 authority made the same finding on their lack of addressing
11 these complaints. So we think it's squarely within his
12 designation. And if he knew about it, he could have said yes.
13 He chose to say he didn't know. I find it hard to believe
14 that's true, which will be a credibility issue for the jury to
15 decide.

16 But that's our argument, Your Honor.

17 SPECIAL MASTER VANASKIE: All right. I'm going to
18 overrule the objection and allow this answer to come in.

19 That takes us to 47-2, line 19.

20 MR. SLATER: This really is the same issue, I think.
21 I don't want to jump in, but I think it's the same issue.

22 MS. ROSE: I disagree with that.

23 SPECIAL MASTER VANASKIE: Go ahead, Nina.

24 MS. ROSE: Thank you.

25 Your Honor, this testimony is very different from the

1 last designation. This is -- as Adam just said, this is a
2 designation that talks about EDQM, so a European regulator and
3 interactions with the European regulator. Judge Bumb expressly
4 held in response to the motion in limine on foreign regulatory
5 issues that foreign regulatory standards, foreign regulatory
6 inspections, what a foreign regulator held is not admissible
7 unless there is some evidence that a defendant, or ZHP
8 specifically in this case, relied on the foreign regulator's
9 statements in some way. And that's not the case here.

10 In other instances we have agreed that foreign
11 regulatory statements have been included in documents that were
12 filed by ZHP. There is just no evidence of that here. This is
13 exactly what that motion in limine precludes.

14 SPECIAL MASTER VANASKIE: All right. I will sustain
15 the objection.

16 MR. SLATER: Your Honor, I don't think I got to argue
17 this one.

18 SPECIAL MASTER VANASKIE: All right. Convince me I'm
19 wrong.

20 MR. SLATER: I don't want to waste your time, but --

21 SPECIAL MASTER VANASKIE: You're not wasting my time
22 at all.

23 MR. SLATER: Okay. So the drug master file amendment
24 in 2013 cites and relies on the European regulations regarding
25 genotoxic impurities. And so we know that the company was

1 bound to comply with their regulations, number one. Judge Bumb
2 ruled that ZHP would have to have been shown to have relied on
3 or known of what the foreign regulatory action or statements
4 were.

5 Here, it's an actual investigation of ZHP's own plant.
6 And if you go into the following section, which is also
7 objected to, 49, line 2 forward, I go through with them the
8 specific deficiencies that were found by the European
9 authority, the company's approach to handling complaints was
10 considered insufficient. That's on line 49, line 7 to 9.

11 And then on 47, line 19 to 23, the system does not
12 record all notifications from customers that deserve
13 investigation as being related to a quality issue, some of the
14 complaints are redefined as inquiries. And then it goes on on
15 the next page to talk about the fact that their records don't
16 reflect all of the complaints that they said they were getting
17 and there's no records of a complaint until May of 2018.

18 So this is an authority that ZHP's own witness last
19 week, their CGMP expert said all of the entities worked
20 together to come up with the common ICH guidelines, they all
21 govern with the same rules.

22 And this goes directly, again, to an authority that
23 they say they were bound to comply with their rules and they
24 relied on their rules and they didn't do so. And, therefore, I
25 think that it would be not barred by any foreign regulatory

1 ruling based on the circumstances.

2 Thank you for listening, Your Honor.

3 SPECIAL MASTER VANASKIE: All right.

4 Nina, I'll give you an opportunity for rebuttal.

5 MS. ROSE: Thank you very much, Your Honor.

6 So there were some misstatements in there. Mr. Slater
7 referred to ZHP referring to a European regulatory statements
8 on genotoxic impurities. This is a foreign regulatory
9 inspection with respect to -- and the findings with respect to
10 customer complaints that has nothing to do with European
11 regulatory guidance on genotoxic impurities.

12 If this comes in, then the motion in limine on foreign
13 regulatory interactions and materials has no meaning because,
14 obviously, ZHP or any other defendant was aware if a foreign
15 regulatory agency inspected them, but the point that the Court
16 was making is that the foreign regulatory standards are not
17 what's at issue in this case. It's FDA standards and what the
18 FDA said. And that is exactly why the Court granted the motion
19 in limine.

20 So if this comes in, then I think it's throwing out
21 the entire ruling on the motion in limine, which I do not
22 believe that is what Judge Bumb intended.

23 SPECIAL MASTER VANASKIE: All right. I'll sustain the
24 objection, as I said before.

25 I think we now go to page 85, line 13, and correct me

1 if I'm wrong.

2 MR. SLATER: You are correct, Your Honor. And I'm
3 going to agree to their counter.

4 SPECIAL MASTER VANASKIE: All right.

5 MS. ROSE: Can I just look at that for one second,
6 Your Honor?

7 SPECIAL MASTER VANASKIE: Sure.

8 MS. ROSE: Thank you.

9 MR. SLATER: I did say I agreed.

10 MS. ROSE: Yeah, I know, but let me look at what
11 you're agreeing to. I just want to make sure. I like to do my
12 due diligence.

13 MR. SLATER: I'll be very transparent, I'm trying to
14 foresee Judge Vanaskie's rulings. I went back through this
15 during the morning hearing and I'm trying to just shorten the
16 hearing. I assumed I was going to lose this one so I --

17 SPECIAL MASTER VANASKIE: I appreciate that.

18 MR. SLATER: No problem.

19 MS. ROSE: Thank you, Your Honor. I just wanted to
20 take a look at it.

21 SPECIAL MASTER VANASKIE: All right. So the
22 counter-designation is in. This is on page 85, line 15 to
23 page 86, line 19.

24 MR. SLATER: And I'm agreeing to the next one as well.

25 SPECIAL MASTER VANASKIE: Okay.

1 MR. SLATER: The one that's tethered to 91-24 to
2 92-20. I'm agreeing to 92-23 to 93-24.

3 SPECIAL MASTER VANASKIE: You've correctly observed
4 the tendency on my part to allow the explanation to come in.

5 MR. SLATER: I have a good career as a defensive
6 coordinator ahead of me.

7 (Laughter.)

8 SPECIAL MASTER VANASKIE: Are you up with us, Nina?

9 MS. ROSE: Yes. Thank you, Your Honor.

10 SPECIAL MASTER VANASKIE: So the testimony at page 92,
11 line 23 to page 93, line 24 will come in.

12 We're now to page 98 and the counter at page 102,
13 line 6 to 103, line 16. Let me get there.

14 So Adam, perhaps you could first let me know where
15 this counter-designation begins and the basis for your
16 objection.

17 MR. SLATER: Okay. So I'm going to start with the
18 testimony that was designated because it literally is a
19 question of answering -- at page 98, line 9, all we asked is
20 that Glenmark Pharmaceuticals, which is one of the string of
21 companies that reported unknown peaks in ZHP's valsartan, all
22 we ask is they're at least the fourth customer to report that
23 information. He says it's another -- yes, they're another
24 customer.

25 And then we ask: To be fair -- and he goes through

1 the email chains. And the question, with Amerigen, Ranbaxy,
2 Vertex, and now we're looking at Glenmark, and the witness
3 confirms, yes, that's what we looked at.

4 That's all the question was, was essentially saying
5 you've been getting complaints about unknown peaks, in general,
6 unknown peaks from all these companies, and he says yes.

7 Then the defense wants to designate part of an answer
8 three pages later without the question and it doesn't even have
9 anything to do with what was asked in the prior question. If
10 you look at the question that was actually asked is -- it's now
11 a new document, not even the subject of the same -- the email
12 that was being asked about on page 98 and 99, we now switch to
13 another document with a different customer and he's about that
14 at the bottom of page 101 in this other email -- I mean, from a
15 different client and they're asked about that they're reporting
16 interference of the toluene peak.

17 We didn't even designate that question. It's
18 completely a different document, a different question, and the
19 defense designates only part of the answer that starts at
20 page 102, line 6 through part of the answer that ends on 103,
21 line 16, this long rambling answer to a completely different
22 question about a different document.

23 It's wholly confusing. Under no interpretation of the
24 completeness doctrine could this ever be remotely considered to
25 be necessary for completeness to show that the answer that was

1 given is incomplete or somehow misleading. The witness
2 simply admitted, yes, those are the customers that we've talked
3 about so far in the deposition.

4 So to inject part of the answer where he's giving all
5 sorts of explanations about different things and then throws in
6 on page 103 a comparison to Glenmark, which is not even
7 something that he was even asked about in that question, it's
8 completely non-responsive to that question. He's being asked
9 in that question about a Sun Pharma email, a completely
10 different thing, and he goes back and starts talking about
11 Glenmark, which isn't even the subject of the question.

12 So for all those reasons, it would be very prejudicial
13 and confusing to insert this testimony in as if it's needed to
14 explain anything when all we asked him to do was confirm the
15 customers we had gone through so far who inquired about unknown
16 peaks as of that point.

17 SPECIAL MASTER VANASKIE: All right.

18 Nina?

19 MS. ROSE: Thanks, Your Honor.

20 So Adam's point he just made about Glenmark is exactly
21 why we designated this as a counter. So there was a question
22 on page 98 about Glenmark being a customer to report an issue
23 of an unknown peak. And the answer was: They're another
24 customer who was asking about the impurity issue with ZHP.

25 As Adam says, they go through the different inquiries

1 and then the question comes up with respect to Sun Pharma on
2 101.

3 It's very clear that on page 102 -- and this is why I
4 designated part of the answer, I'm happy to designate the
5 question too and designate this whole string. I was trying to
6 keep it as brief as possible because plaintiffs have said they
7 don't want to have a lot of additional testimony to increase
8 their times, but I'm happy to be more fulsome.

9 The witness is clearly going back to the question
10 about Glenmark. It's that -- he said: Counsel, you asked the
11 question is somehow related all these -- that somehow relate to
12 all these impurities and group them into the same inquiry; for
13 example, that all of these -- he's trying to clarify that all
14 of these different peaks -- when he said "the impurity" or "the
15 issue," he wasn't trying to say that all of these complaints
16 were about the same peak, and that's what he's trying to
17 clarify: But like I said, I do not recall whether they're the
18 same inquiry, not even of the same nature, that's one thing.

19 That's really the key point is that he's just trying
20 to clarify that when earlier he said that all these companies
21 complained about the impurity, it is not one impurity. I mean,
22 that's just demonstrated by the record. It's multiple
23 impurities.

24 I'm happy to designate the question that starts on
25 101-21, just for clarity, and then goes through 102 -- even

1 if -- I would be happy to stop it at 102-12. All I care about
2 is the witness was trying to go back in time, was trying to
3 say, wait a second, I said something earlier and I want to
4 clarify it. I don't know that these were the same impurities,
5 that this was the same inquiry that was being made by multiple
6 companies.

7 And I don't think there's any dispute about the fact
8 that different companies made different inquiries about
9 different peaks, that they weren't all just the exact same peak
10 that every company was inquiring about. I think that's what
11 the witness is trying to clarify.

12 So I'm not trying to add anything. I'm happy to be as
13 concise as possible with it just to make that point.

14 SPECIAL MASTER VANASKIE: All right. I don't think
15 the designation -- the counter-designation is necessary for
16 purposes of completing the witness's answer. I'll sustain
17 plaintiffs' objection.

18 Next one begins on page 120, line 23. And this really
19 goes to the counter, I take it. Well, there's a defendant
20 objection as well.

21 MR. SLATER: I'll let them have the counter here.

22 SPECIAL MASTER VANASKIE: All right.

23 MR. SLATER: We're going to drop our objection to the
24 counter. They can have that counter.

25 SPECIAL MASTER VANASKIE: Okay. So 121, lines 1 to 10

1 is in.

2 MS. ROSE: Your Honor, can I clarify with Mr. Slater?

3 SPECIAL MASTER VANASKIE: Sure.

4 MS. ROSE: So I had our designations starting at 121-1
5 because your designations stopped at 124 -- sorry.

6 MR. SLATER: Yes, I agree, you can have the rest of
7 the sentence.

8 MS. ROSE: Okay. Great. I just wanted to --

9 SPECIAL MASTER VANASKIE: All right. Good.

10 MS. ROSE: So all of 120, line 24 would come in and
11 then all of 121, line 1 through line 10 would come in.

12 SPECIAL MASTER VANASKIE: Correct.

13 MS. ROSE: That is correct?

14 MR. SLATER: Correct.

15 MS. ROSE: Thanks.

16 SPECIAL MASTER VANASKIE: All right. Next we are up
17 to page 140, line 18.

18 MS. ROSE: Your Honor, I can maybe shortcut this.

19 I understand from prior rulings, and we noted this in
20 our chart, that the Special Master has indicated he's inclined
21 to allow such questioning, but I wanted to make our objection
22 for the record on that.

23 So I just wanted to note that we recognize that this
24 is probably something the Special Master would let in, but we
25 would like to preserve the objection.

1 SPECIAL MASTER VANASKIE: Yes, I will allow this
2 testimony to be presented. So the record is clear, from 140,
3 line 18 to 140, line 21, is in. That's the question. And the
4 answer is at line 24.

5 MR. SLATER: And I think that covers the next two on
6 the list, too. That's just the same issue, right? It's the
7 same set of questions, Nina?

8 MS. ROSE: Yes, I agree that would apply to our
9 objections through line -- sorry, through page 141, line 10.

10 SPECIAL MASTER VANASKIE: So where are we at now? I'm
11 confused.

12 MR. SLATER: We're at 152, line 19, Judge. I know,
13 it's hard to deal with when we start agreeing to things. It's
14 going to throw off your whole mojo.

15 (Laughter.)

16 SPECIAL MASTER VANASKIE: 152, line 19. So this is
17 dealing with mischaracterization or alleged mischaracterization
18 of an email, I take it?

19 MS. ROSE: Yes, Your Honor.

20 SPECIAL MASTER VANASKIE: Yes, I will overrule the
21 objection and allow this testimony from 152, line 19 to 153,
22 line 5 to be presented.

23 We're now at 153, line 11 --

24 MR. SLATER: This is all the same line of questions so
25 I think it would cover everything through page 153, line 24,

1 but I'll ask Nina to confirm.

2 MS. ROSE: I agree that they are the same issue, the
3 question and the answer.

4 SPECIAL MASTER VANASKIE: Okay. I have the same
5 ruling.

6 MR. SLATER: And I think 159, 4 to 9 and 12 to 13 is
7 the same issue as well.

8 MS. ROSE: Let me take a look, Your Honor.

9 SPECIAL MASTER VANASKIE: Yes, absolutely.

10 MS. ROSE: Your Honor, it is the same issue, but I
11 just want to raise the fact that here, again, it's an express
12 representation about what the email says and that is contrary
13 to the text of the email. I respect your ruling, I just want
14 to make that clear that our objection is that this states that
15 the email says something that it does not say.

16 SPECIAL MASTER VANASKIE: All right. I'll have the
17 same ruling and this will come in.

18 MR. SLATER: And I hate to steal your thunder, Judge,
19 but I'm going to agree to their counter at 272, line 2 to 8;
20 their counter is 270, line 22 to 271, line 5. And I'm agreeing
21 to that. We're going to drop our objection to that.

22 SPECIAL MASTER VANASKIE: All right. So the testimony
23 from 270, line 22 to 271, line 5 will come in. And that
24 completes Mr. Jie Wang's deposition.

25 And then I have as the final ZHP witness, and correct

1 me if I'm wrong, but it would be -- is it Lijie Wang?

2 MS. ROSE: It's Lijie Wang, Your Honor. Thank you.

3 SPECIAL MASTER VANASKIE: Lijie Wang, thank you. Let
4 me find her testimony.

5 So we're at the Lijie Wang deposition of January 26th,
6 2021. And the first area in dispute begins at page 78.

7 MS. ROSE: Your Honor, this may be something we can
8 shortcut because our objection relates to the issue of general
9 causation and its role in the trial giving references to
10 genotoxicity and cancer. So I don't think that's something --
11 I think we've agreed that that's something that Judge Bumb has
12 before her and is going to need to weigh in on, but for
13 purposes of preserving the record, we wanted to include that
14 here.

15 SPECIAL MASTER VANASKIE: All right. Do you agree,
16 Mr. Slater, we defer this to Judge Bumb?

17 MR. SLATER: I agree that it should be admitted and I
18 agree that the defense has submitted something to Judge Bumb
19 and I just got a chance to see it actually this morning. But I
20 do believe she's going to address that question. I don't agree
21 that this implicates general causation, but I'm fine with
22 waiting -- I mean, Judge Bumb is going to definitely address
23 this question that's been put in front of her. So, yeah, I
24 think the testimony should be in, subject to whatever Judge
25 Bumb does.

1 SPECIAL MASTER VANASKIE: All right. We'll say the
2 testimony is in, subject to Judge Bumb's ultimate
3 determination.

4 All right. So I've moved now to page 80, line 3. The
5 question goes to line 8. I have a conditional
6 counter-designation. It also carries over to 80, line 11 to
7 16, which is the answer.

8 MR. SLATER: I will agree to their counter.

9 SPECIAL MASTER VANASKIE: And this is the counter at
10 79, lines 12 to 16? Do I have that right?

11 MR. SLATER: You're right, Judge, 79, lines 12 to 16,
12 and 79-19 to 24. That's their counter and I'm agreeing to it.

13 SPECIAL MASTER VANASKIE: All right. Anything else on
14 this, Nina?

15 MS. ROSE: Yes, Your Honor.

16 We also have an objection to the testimony as
17 designated first for the reasons we just discussed, the
18 references to genotoxic impurities that pose a risk to human
19 health and injecting general causation into the trial, which we
20 will discuss with Judge Bumb.

21 And then also on the point that this question of
22 whether Princeton is not allowed to sell and never been allowed
23 to sell drugs in the United States that have impurities, that
24 is a question that goes to expert regulatory testimony as to
25 whether impurities are permitted in drugs at certain levels;

1 and at the time that valsartan was being sold, whether that was
2 permissible.

3 SPECIAL MASTER VANASKIE: Go ahead, Mr. Slater.

4 MR. SLATER: Thank you, Judge.

5 The question actually was not asked as imprecisely as
6 stated by counsel. I know you were paraphrasing, I'm not
7 accusing you of anything.

8 The question was directly within her topics -- one of
9 her topics under the heading of Process Development was ZHP's
10 evaluation and knowledge of the health risks of nitrosamines,
11 including NDMA and NDEA, including, but not limited to, as a
12 contaminate of ZHP's valsartan API and ZHP's valsartan finished
13 dose. This falls directly within her designation.

14 The question is, does she agree that Princeton isn't
15 allowed to sell and never has been allowed to sell drugs in the
16 United States that have genotoxic impurities -- NDMA and NDEA
17 are genotoxic impurities, I don't think anyone is going to
18 dispute that -- that pose a risk to human health? That's
19 literally the language in the regulatory guidances that ZHP
20 agrees applied to their conduct, that's what the guidances say.
21 They say that genotoxic impurities should not be in these
22 drugs. I'm paraphrasing those guidances but that is the core
23 of why this was never allowed. And I don't see how that
24 question could be inappropriate.

25 The witness answers: We want to ensure our product

1 meets the guidance on the risk assessment based on FDA
2 guidance, including the topic impurities.

3 I mean, she's saying to me, yes, we have to follow the
4 guidances.

5 So I'm not really sure how it can be that this is
6 expert opinion when this is a court-approved, court-ordered
7 designation topic for a corporate representative for a company
8 that is required by law to understand the risks of genotoxic
9 impurities and is deemed to be an expert in its field and needs
10 to understand it and they had to designate someone to speak for
11 their company about their understanding of what they were
12 supposed to do in addressing genotoxic impurities,
13 nitrosamines, et cetera.

14 SPECIAL MASTER VANASKIE: Nina, any response?

15 MS. ROSE: Yes. So I think Mr. Slater just raised
16 another issue.

17 So I think he's focusing on the fact that the witness
18 was designated to talk about Princeton's knowledge of health
19 risks. So that for reasons we've discussed, that's the general
20 causation issue, but the witness is not designated to talk
21 about what the regulatory guidances say with respect to whether
22 a manufacturer is ever allowed to sell a medication that may
23 have a genotoxic impurity in it. We know because the FDA does
24 allow NDMA and NDEA up to some limits even today.

25 So this -- the question is just false. It's a

1 misleading question on its face and it's being posed to an
2 expert -- I'm sorry, being posed to a fact witness who is not
3 an expert in what is required and was not designated to testify
4 about what is required under the FDA regulations.

5 SPECIAL MASTER VANASKIE: And you had a conditional
6 counter at page 79, line 12 to 16?

7 MS. ROSE: I believe that -- did we just address that
8 counter?

9 MR. SLATER: 12 to 16 and 19 to 24. And I've agreed
10 to those counters.

11 SPECIAL MASTER VANASKIE: Subject to Judge Bumb's
12 ruling on general causation, I will allow this question and
13 answer to be presented.

14 Now we go to page 145.

15 MS. ROSE: Just for the record to be clear, Your
16 Honor, there was an objection to 80, lines 11 through 16. I
17 believe that would be encompassed within Your Honor's ruling
18 with respect to the previous designation.

19 SPECIAL MASTER VANASKIE: Yes, it is encompassed
20 within that. All right?

21 So there's an objection to the testimony that appears
22 on pages 145 and 146 based upon Federal Rule of Evidence 407 as
23 a subsequent remedial measure. I have a note here that says
24 "needs further discussion for context."

25 So Nina, maybe you can elaborate on your objection.

1 MS. ROSE: Sure, Your Honor. So this is an email that
2 was sent in September of 2018, after the recall, after the
3 discovery of NDMA. There's no product on the shelves at this
4 point. It's from someone at Princeton who is explaining that
5 there is going to be a training seminar and the training topic
6 will be genotoxic impurities, regulatory requirements,
7 qualifications, and control strategy; and that is a remedial
8 measure taken in direct response to the finding of NDMA and the
9 recall.

10 Here, the company is trying to make sure that everyone
11 is educated on what's going on. So this is the issue.

12 Introducing this and introducing this to the jury, it
13 seems like some sort of admission or what it's going for is
14 that there's some sort of admission that was something was done
15 wrong that needed to be corrected through additional training.

16 It seems to me that this email is just being
17 introduced to lay the foundation to the attachments to the
18 email and I think that can be done without discussing the
19 contents of the email.

20 SPECIAL MASTER VANASKIE: Adam?

21 MR. SLATER: Yes, Judge. A subsequent remedial
22 measure can never include a situation where the party that's
23 invoking Rule 407 was already under an obligation to do
24 something or was coerced by the regulatory regime or by an
25 outside actor to do what they were doing.

1 And in this case, they were always required by the
2 regulations that controlled their conduct from day one all the
3 way through the end to understand what they're supposed to do
4 with genotoxic impurities, what the regulatory requirements
5 are, the qualifications, the control strategies. This was
6 always something that they were required to do.

7 The fact that they had a seminar doesn't change that
8 they were obligated to do it by law, not that they, out of the
9 goodness of their hearts, went to the movie theater and said,
10 hey, somebody tripped, let's go check the carpet there and
11 let's fix the carpet and actually take steps to fix the carpet.
12 And Your Honor reminded me of that in the arguments that were
13 happening with Teva, that the question is what are they
14 actually doing.

15 The fact that they're training people on what the
16 requirements are is not -- I remember the movie theater example
17 because I think I learned that one in law school -- that the
18 subsequent remedial measure is we want to encourage people to
19 actually fix the carpet so somebody doesn't trip over it in the
20 next movie.

21 This is something they were required to do all along
22 by the regulatory laws. There's nothing remedial about it.
23 All it says is that there's a seminar and then it does kick in
24 to the attachments where we look at some of the things that
25 people were being told factually to show that these were true

1 statements and these were the things that they were governed
2 by.

3 But it's certainly not a subsequent remedial measure
4 that they are having a meeting to talk about what they always
5 needed to do.

6 SPECIAL MASTER VANASKIE: So I will allow the
7 testimony at page 152 -- I am sorry, page 145, line 6 to 14.

8 Now I think we go to page 152.

9 MR. SLATER: Yes.

10 SPECIAL MASTER VANASKIE: Lines 19 and 20.

11 152, line 23, 153, line 9.

12 MS. ROSE: Your Honor, if it helps, our objection is
13 based on the general causation outstanding question.

14 SPECIAL MASTER VANASKIE: Yes, and I think until that
15 issue is resolved by Judge Bumb, this would not come in. In
16 other words, however she decides it will determine whether it's
17 admissible.

18 MR. SLATER: But it's admissible subject to her
19 ruling? It's admitted subject to her ruling?

20 SPECIAL MASTER VANASKIE: Yes, subject to her ruling
21 it's admissible.

22 MR. SLATER: Okay.

23 And I can tell you on the next one, which I think is
24 the answer, 152-23 to 153-9, they have a counter at 12 to 14 on
25 page 153. I agree to that counter.

1 SPECIAL MASTER VANASKIE: All right.

2 MS. ROSE: And Your Honor, for the record, there was
3 also an objection on the general causation issue there.

4 SPECIAL MASTER VANASKIE: Yes. Again, dependent upon
5 Judge Bumb's ruling.

6 MS. ROSE: Thank you, Your Honor.

7 SPECIAL MASTER VANASKIE: We're now to page 166, lines
8 11 to 16. And this deals with the carcinogenic risk posed by
9 NDMA. Is this also now subject to Judge Bumb's ruling?

10 MS. ROSE: Yes, Your Honor. And for clarity, because
11 it might just be easier, the subsequent designation I believe
12 picks up right after this. 166, line 11 to 16 is designated.

13 SPECIAL MASTER VANASKIE: Right.

14 MS. ROSE: And then 166, 19 to 23. Maybe I'm confused
15 about -- oh, it starts at the "acceptable." Sorry. I just
16 want to orient myself.

17 Adam?

18 MR. SLATER: Yes, I'm orienting as well.

19 MS. ROSE: Okay. No, I just wanted to know what -- it
20 looks like you cut part of the answer or part of the question.
21 I just wanted to be clear on what that was.

22 MR. SLATER: Yeah. I mean, I had taken out what the
23 EMA criteria was. I think that where we are now, I'll let you
24 choose. If you don't want it in, it won't go in. If you want
25 it in, those three lines can go in. It's dealer -- you're the

1 dealer. You're in charge. I don't really care. I'm happy to
2 use the entire answer. I think it's appropriate, but if you
3 want it as designated, it's fine also.

4 MS. ROSE: I don't think taking out those three lines
5 resolves our objection to it, so I --

6 MR. SLATER: I would agree.

7 MS. ROSE: That would be part of our objection. So
8 that's fine, we can leave it as is.

9 So in addition --

10 MR. SLATER: So we'll make it the entire answer.
11 We're not going to cut out those two lines. That's what you
12 just said, right?

13 MS. ROSE: Sure. I think -- yes, I think that the
14 objection, if it includes those lines, it just makes -- we
15 object to those lines for the same reasons.

16 MR. SLATER: Yep.

17 MS. ROSE: So in addition to the general causation
18 issue, Your Honor, our objection is also that this is referring
19 to a post-recall document that talks about post-recall
20 standards and, as designated, it misleadingly suggests that the
21 limits -- the FDA limits for NDMA and valsartan existed at the
22 time that the API was manufactured. These are standards
23 adopted after the recall and that are referenced only in a
24 post-recall document.

25 SPECIAL MASTER VANASKIE: And so your position would

1 be that none of this comes in?

2 MS. ROSE: Our position would be that this reference
3 here to this document, which is a post-recall document, and
4 talking about the standards that exist for NDMA, is
5 unnecessarily confusing because it is unclear to the jury,
6 who's not oriented at the time of this document or the date of
7 this document, suggesting that there were standards in place
8 for the acceptable limit of NDMA as 0.3 parts per million prior
9 to the discovery crime of NDMA in 2018.

10 SPECIAL MASTER VANASKIE: Adam, your response?

11 MR. SLATER: Yes. Thank you, Judge.

12 This argument -- which I think it's a new argument
13 that something that's a post-recall document somehow is
14 problematic -- I don't understand what evidentiary rule would
15 actually say that. There's a whole host of post-recall
16 documents, including the Deviation Investigation reports, et
17 cetera, et cetera, et cetera, are all admissible because these
18 are the documents that are analyzing what occurred.

19 I'm not really sure what the substance of the argument
20 would be. They cited Rule 403. This is their document and the
21 document is identified on page 163, Judge. It's introduced.
22 It's Exhibit 60, the Valsartan Risk Evaluation for its
23 Optimized Process. Because what ZHP did is when they found out
24 that the limits for how much you could put into these drugs of
25 NDMA and NDEA were going to be much higher than what they

1 hoped -- I mean, much lower than what they hoped, they then
2 immediately said we got to figure out a way for our business
3 purposes to get the NDMA out so we could go to the FDA and say,
4 hey, we could do this. And they came up with a process where
5 they quenched the solution basically outside the presence of
6 the drug product so that when they quenched the sodium azide,
7 it wouldn't cause the contamination of the product with the
8 NDMA. They basically were pulling out part of it, do it over
9 here. That's what their optimized process -- they did this on
10 their own. This wasn't to remediate anything. It was so that
11 they could keep selling the drug. It wasn't to fix a problem
12 for the world, and there's no witness that ever suggested it
13 was a remedial measure. So -- and by the way, they were
14 already obligated under the federal regulations to have done
15 that to begin with. So again, it can't be a subsequent
16 remedial measure because they were always required to identify
17 and control any genotoxic impurities and if they found them, to
18 then go to the FDA and say we want to propose a level that we
19 can allow to be in here. Without doing that, no level was
20 allowed before this happened because you had to actually ask
21 for permission and justify how much you were going to allow to
22 be there. They never did that.

23 So they cited Rule 403. There's no way that this is
24 unconfusing or anything. It's their document, the language of
25 their document. If they want to bring in a witness to come and

1 talk about that document and say, Well, let me tell you what
2 the significance of that document is, they can do it. But
3 we're literally working with their own document that
4 specifically speaks to the NDMA and the fact that it's a
5 carcinogenic risk substance, which we obviously don't agree
6 that implicates general causation. But that's really the issue
7 that counsel is looking to hold. I don't think there's any
8 valid reason to keep this out.

9 SPECIAL MASTER VANASKIE: Nina, any response?

10 MS. ROSE: Yes. Thank you, Your Honor. So just very
11 quickly, Mr. Slater's response didn't have anything to do with
12 our objection. That was just a long colloquy of trying to
13 inject their theory of the case on -- with respect to ZHP's
14 actions following the recall.

15 But our objection is a 403 objection because this is
16 misleading and confusing to the jury. Mr. Slater just said
17 that this email chain, that was a meeting to address the issue
18 of NDMA in valsartan after it was discovered, after the product
19 was off the shelves, and this is a document that was created
20 after 2018. And so Mr. Slater said earlier that the documents
21 that were discussed were documents that predated the recall.
22 This is a document that postdates the recall and he is quoting
23 it to say that there were standards in NDMA that did not exist
24 during the time where ZHP's conduct is at issue. And so I
25 think it is confusing to the jury as to whether these limits

1 existed at the time or did not.

2 SPECIAL MASTER VANASKIE: All right. I'm just trying
3 to see where this starts and where it ends. Let me see if I
4 have this right.

5 Adam, you've designated 166, line 19 to 166-23.

6 MR. SLATER: Line 11 to 23, Your Honor.

7 SPECIAL MASTER VANASKIE: Line 11 to 23. Well, that
8 makes sense. That's where the question begins, line 11.

9 MR. SLATER: It goes from 11 to 23, Your Honor, and
10 then the answer is 167, line 2.

11 SPECIAL MASTER VANASKIE: And the answer is simply:
12 Yes, I see it.

13 MR. SLATER: Correct. And then I go from there to ask
14 him questions on the next page that are not objected to, I
15 don't believe.

16 SPECIAL MASTER VANASKIE: So what is being --

17 MR. SLATER: Oh, no, they are objected to. So you'll
18 see it on 168 when I ask questions of her about this, which was
19 one of her topics, the contamination levels and their
20 evaluation and knowledge of the risks of those levels.

21 SPECIAL MASTER VANASKIE: Yes. I really -- I know
22 I'm -- I'm really having trouble because the witness -- the
23 answer that comes in at 168, line 13 to 15 is: Yeah, I
24 remember the document that you showed me a table. I don't see
25 anything substantive there.

1 MR. SLATER: Well, the question is at 168, line 5 to
2 10. This is a few objections down. This is another entry.
3 But the question is 168, line 5 to 10 going through -- this is
4 all a line of testimony -- because what we anticipated, Your
5 Honor, was that the defense might argue, well, there were no
6 levels at the time that were set by the FDA at the time --

7 SPECIAL MASTER VANASKIE: Right.

8 MR. SLATER: And you remember we talked about that the
9 other day, there was a counter that defense wanted that said
10 there were no limits before 2018 and I was concerned that that
11 was too ambiguous and I was overruled on that and that counter
12 came in.

13 So now I'm asking them about their analysis. Even if
14 those new levels were applicable, they were massively exceeded
15 by the levels of contamination. So we get it both ways. It
16 was never allowed. But even if those levels existed, you still
17 far exceeded those levels. And that's what I'm establishing
18 here with this witness, which goes to, obviously, the value of
19 the product because if it's over the levels, you can't sell it,
20 our position is.

21 MS. ROSE: Your Honor, may I respond to that?

22 SPECIAL MASTER VANASKIE: Yes, you may.

23 MS. ROSE: I don't want to break your rules about the
24 number of responses.

25 So I think what Mr. Slater said just clarifies what

1 our concern is here, which is that plaintiffs continue to
2 insist that there were -- that there was a limit or a level
3 prior to 2018 when the FDA set a limit, and here they're asking
4 about a post-2018 or post-recall document and talking about the
5 limits and walking a witness through the limits that were set
6 in 2018. But there's no dispute that there were limits set in
7 2018 and there's also no dispute that the levels were above the
8 limits set in 2018. That's why the product was recalled. So
9 the only reason to bring this in is to suggest to the jury that
10 these limits were in place prior to the recall. I don't
11 believe that there's a reason to set the standard -- I mean,
12 this document says what the document says. And walking a
13 witness through it, the only reason to do it is to suggest that
14 these were limits that were in place prior to 2018.

15 MR. SLATER: I'm raising my hand.

16 SPECIAL MASTER VANASKIE: You may be heard.

17 MR. SLATER: You know, Judge, I've heard this several
18 times now, this suggestion that we're going to try to trick the
19 jury into thinking there were levels in place before the
20 recall. We're on the record now. We are never going to try to
21 do that. Why would we when the levels -- when no levels were
22 allowed before that? Of course we're not going to do that.
23 And there's no juror in the world that's going to not
24 understand -- because we're all going to explain it, there were
25 no levels before 2018 that were allowed, it was only after that

1 levels were set. And guess what? Even when those levels were
2 set, the levels of contamination far exceeded what the FDA said
3 was acceptable even after the fact.

4 So that's what we're doing here. We're quantifying
5 the level of contamination. Nobody is trying to mislead the
6 jury. Nobody could ever succeed at misleading the jury.
7 Nobody in the world could believe that at the end of the
8 opening statements the jury is not going to understand what
9 occurred because we're all going to adhere to the facts of what
10 occurred and that's not the only interpretation that we're
11 trying to trick the jury into thinking those levels existed
12 because that's not what we're doing. We're literally asking
13 questions about the actual language in the document where they
14 evaluated the levels and the risk.

15 Thank you, Judge.

16 MS. ROSE: Your Honor, apologies. Can I just have one
17 minute?

18 So I don't -- there is no intent requirement in 403.
19 I don't think our argument is that plaintiffs are intentionally
20 trying to trick the jury. We're dealing with a canned video
21 that is going to be cut up and sliced together and put before a
22 jury and also the plaintiffs have taken the position that
23 defendants would have to bring this witness live from China,
24 even though they are playing the tape, if we wanted to have a
25 chance to clarify any of this and then, presumably, I assume

1 plaintiffs are arguing they would then have another chance at
2 cross-examination.

3 MR. SLATER: She's in New Jersey, Nina.

4 MS. ROSE: Okay. I apologize. But the point remains
5 is that we would have to bring a witness that -- if she's in
6 New Jersey, you could call her to testify if she's within the
7 subpoena power of the Court. The Court has said you don't have
8 to do that and that you could play testimony because we're
9 trying to limit the length of this trial.

10 But we have to understand the repercussions of that,
11 which is that when you put up all this testimony cut up
12 together, not as it was presented, there is a risk that the
13 jury is going to going to be completely confused by this
14 document when presented in a long string of other documents
15 that you're saying are pre-2018. So that's the issue.

16 It's not -- I'm not saying that plaintiffs are
17 affirmatively trying to trick anyone. It's that you have to
18 look at whether this is confusing as presented, and these are
19 clipped-up questions and answers that when put together I think
20 there's confusion that could come before the jury. And
21 plaintiffs have experts who can talk about this, who can
22 explain the levels and say that they were above it. I don't
23 think anyone's going to disagree with what the facts are on
24 what the levels were in 2018. So that's my concern. I'm not
25 trying to accuse plaintiffs' counsel of misleading anyone or

1 trying to mislead anyone. I'm just dealing with the fact that
2 we are dealing with a transcript that is going to be cut up
3 instead of a live witness.

4 SPECIAL MASTER VANASKIE: I think the problem here is
5 just that we're dealing with a transcript that's going to be
6 cut up and that gives you all the opportunity to dissect each
7 and every word and say, oh, this is going to become the
8 centerpiece of the trial when it's not the case. It just is
9 part of the evidence that's being presented. It's just a
10 question of whether it's unduly prejudicial or causes confusion
11 for the jury. And I don't see it. So I will allow this to
12 come in.

13 Going forward, I'm going to read the excerpts out loud
14 because maybe that will help, but I just don't see this as
15 meriting as much attention as it's receiving today.

16 MS. ROSE: Understood, Your Honor. ZHP defendants
17 just wanted to make the record that we have issues with the
18 designations as they were cut and being used in lieu of live
19 testimony for a witness who's available to be called. But I
20 appreciate your ruling and I think that actually will resolve
21 many of the remaining designations.

22 SPECIAL MASTER VANASKIE: Okay. The next one I have
23 begins on -- and correct me if I'm wrong. If I miss something,
24 you have to tell me. But I have it beginning on 169, lines 19
25 to 22.

1 MR. SLATER: There's just one page before that -- or a
2 couple pages before that, unless they're being -- but I
3 think -- I'm going to go out on a big limb -- I think that
4 everything on 168 and 169 is encompassed by what Your Honor
5 just ruled.

6 MS. ROSE: I would agree, but I -- and also I'm glad
7 you raised that because I want to clarify.

8 So the objections that we had to this testimony
9 starting on 169, there was an evidentiary objection --

10 MR. SLATER: Don't forget 168.

11 MS. ROSE: Oh, apologies.

12 MR. SLATER: Or maybe that was addressed by Your
13 Honor's ruling before because we did talk about it. I
14 apologize if I'm jumping the gun on that.

15 MS. ROSE: I just wanted to note that our objection
16 included the -- some of our objections here include the
17 genotoxic impurity and the general causation issue. I just
18 wanted to make sure that that's preserved.

19 SPECIAL MASTER VANASKIE: That is preserved. I want
20 to make that clear. I haven't ruled on that issue and I have
21 not done so because I believe that's a matter for Judge Bumb.

22 MS. ROSE: Thank you, Your Honor.

23 MR. SLATER: I think that covers all of the objections
24 through page 170; is that correct?

25 MS. ROSE: Let me take a look. I believe that's

1 correct.

2 SPECIAL MASTER VANASKIE: So are we up to page 239
3 now?

4 MR. SLATER: Yes.

5 SPECIAL MASTER VANASKIE: So on page 239, beginning at
6 line 21 and going to page 240, line 8 --

7 MR. SLATER: We're going to drop that. We're going to
8 drop that designation.

9 SPECIAL MASTER VANASKIE: Okay.

10 MR. SLATER: And I'll tell you why, Judge, and for the
11 record, because even though I think it's still a matter of
12 risk, because it says at the top of page 240 "May likely have
13 adverse effect over long-term exposure," I'm going to be
14 exceedingly cautious and I'm going to drop that designation.

15 SPECIAL MASTER VANASKIE: All right. So that takes us
16 through 240, line 14.

17 MR. SLATER: And that's the answer then, so I'm
18 dropping that as well, Your Honor.

19 SPECIAL MASTER VANASKIE: All right. Then I have
20 counter-designations. I don't know if we've addressed them or
21 not.

22 MS. ROSE: Your Honor, I would like to raise that --

23 MR. SLATER: I don't think there's any counters to
24 those.

25 MS. ROSE: Oh, no, there's no counters, no.

1 Mr. Slater is correct, there's no counter-designations for the
2 designations at 239 and 240.

3 So I think that takes us to the end of the ZHP
4 witnesses, but I just wanted to raise one point before we move
5 on, if that's allowed?

6 SPECIAL MASTER VANASKIE: Sure.

7 MS. ROSE: Thank you, Your Honor.

8 We have not -- and I believe we addressed this on last
9 Friday's hearing but, again, I just want to continue to make
10 the record. We have not discussed whether -- we've not
11 discussed any affirmative designations from deposition
12 testimony by ZHP witnesses. This has been an ongoing issue and
13 I think other defendants might also have the issue.

14 It's our understanding that plaintiffs are taking the
15 position that ZHP is not allowed to affirmatively designate
16 anything from ZHP witnesses. If that's not the case, please
17 correct me, Mr. Slater.

18 MR. SLATER: First of all, I'm not really sure what
19 affirmative designations counsel is talking about because we've
20 only been served with affirmative designations for one ZHP
21 witness, that was Jucai Ge, who they are bringing in live. So
22 because she's coming live, they would not be playing her
23 testimony and I think we all agree to that. So I don't think
24 there are any affirmative designations for ZHP. And I
25 certainly assume that counsel is not suggesting that they're

1 going to go back to the drawing board and start serving
2 affirmative designations on us a month before trial. So I'm
3 assuming that's not what they're planning to do.

4 As far as the general rule for how affirmative
5 designations are handled across the board for trials, and we've
6 submitted the brief and we sent a copy of it to Your Honor, the
7 briefs that were filed by both sides, in fairness, if the
8 defense wants to present testimony of witnesses that they have
9 under their, quote/unquote, control and the case law explains
10 what that means, such that they're available, then they have to
11 bring the witness live. It's their witness. So if they want
12 to put their witness before the jury, they're not allowed to
13 shield the witness from cross-examination. They would have to
14 bring the witness live.

15 If the witness is unavailable and they could actually
16 meet the standard that the case law lays out, then they could
17 play affirmative designations if they had done them already in
18 their case in lieu of bringing the witness live because that's
19 their case, their presentation and if the Court is satisfied
20 the witness is truly unavailable, then they would be allowed to
21 do that. They would not be allowed to put their own case into
22 our case. That's our position.

23 I don't think we have that issue with ZHP because
24 there are no affirmative designations from ZHP. And, again, we
25 would have a very serious problem if parties were to start to

1 serve new designations on us to try to give us new testimony to
2 grapple with now a month before trial.

3 So I don't know if that answers what counsel was
4 raising, but I don't think it's a ZHP issue because there are
5 no affirmative designations at issue.

6 SPECIAL MASTER VANASKIE: Nina?

7 MS. ROSE: Just to respond to that, there are, because
8 we had affirmatively designated Jucai Ge's redirect, which you
9 acknowledged earlier that we let you know that we were
10 addressing that. I was just noting that we had not addressed
11 those designations yet and so that -- I was noting those for
12 the record.

13 In addition, there are a couple of other witnesses who
14 do have redirect testimony on -- very brief in their -- I raise
15 this because Jie Wang is one of them, as I was just looking at,
16 very limited redirect testimony that was made at their
17 deposition. And there's no time limit that has passed if we
18 wanted to designate affirmatively anything. I just wanted to
19 discuss that point.

20 I believe that the Court said that designations need
21 to be served like -- or resolved two weeks prior to trial. So
22 I don't -- I think if we submitted -- and I'm not sure yet if
23 we need to, it was really depending on what came in from
24 plaintiffs' affirmative designations and whether we had
25 something to respond to and based on what the Court allowed.

1 So I don't think it's fair to say that we are not
2 allowed to designate affirmative testimony that takes into
3 account the Court's rulings and plaintiffs' designations which
4 they've significantly cut in the last month.

5 MR. SLATER: I guess if they want to raise something,
6 we'll deal with it at that time. Right now there's nothing in
7 front of us. And Jucai Ge is coming to Court, so I'm not sure
8 why counsel thinks they can play a video for the witness
9 affirmatively and put the witness on the stand affirmatively in
10 their own case. The case law clearly says that if the witness
11 is available to the party that wants to bring the witness in,
12 they have to bring the person live, if they're available.

13 MS. ROSE: Your Honor, I disagree with that. I think
14 we are in a different world now. Judge Bumb had initially said
15 she wanted people brought live when -- in plaintiffs' case,
16 that plaintiffs should bring witnesses live. And plaintiffs
17 then argued and convinced Judge Bumb that it would be easier in
18 this case for them to present videotape testimony despite the
19 fact that we had offered to bring Jucai Ge live.

20 Now what they are saying is because we offered to make
21 witnesses in China available to them, they are allowed to play
22 their deposition testimony. But if we want to have any
23 response from that witness, we need to fly the witness from
24 China to the United States and testify live. And then
25 presumably plaintiffs are going to argue that they get another

1 bite at the apple and get to cross-examine that witness, which
2 is only going to lengthen the trial.

3 I think that this -- across the board, that a witness
4 that has been offered to plaintiffs as a live witness and they
5 have rejected and want to use deposition testimony, that we
6 can't also use deposition testimony to limit the length of the
7 trial.

8 MR. SLATER: I thought we --

9 (Simultaneous speakers.)

10 SPECIAL MASTER VANASKIE: You can use deposition
11 testimony, but you've got to make your designations soon. You
12 know, you can't drag this out.

13 MS. ROSE: We did not intend to, Your Honor. We've
14 already made the designations for Jucai Ge, which is the
15 witness who had the longest redirect. The only -- I don't know
16 that we have any other designations. Once Your Honor ruled on
17 their affirmative designations, I just need to look very
18 quickly to see if there are any affirmatives that respond to
19 things that Your Honor said could come in.

20 SPECIAL MASTER VANASKIE: All right. Very well.

21 MS. ROSE: Thank you, Your Honor.

22 MR. SLATER: I guess I'll reserve all my rights. I
23 don't know what I'm dealing with right now. We filed our brief
24 long before the first trial date. This isn't some kind of a
25 change in position. This is just, unfortunately, what the

1 federal rules require and the case law, so we're just following
2 that.

3 SPECIAL MASTER VANASKIE: All right. Anything else on
4 the Chinese witnesses?

5 MR. SLATER: Not for today, Your Honor.

6 SPECIAL MASTER VANASKIE: Or ZHP witnesses?

7 MR. SLATER: And we have some others that I think will
8 be coming to you. And it's -- I think we have another hearing
9 tomorrow, if you have time for us, we have a few more witnesses
10 that should be ready for you tomorrow.

11 SPECIAL MASTER VANASKIE: Well, get it to me as soon
12 as you can. I'll see what I can do in terms of being ready for
13 it.

14 We'll go back to the Teva witnesses now.

15 MR. SLATER: And if not, Judge, you can just let us
16 know that you want to do it a different time. Maybe we'll
17 email it to you and you can maybe let us know tonight whether
18 or not you want us tomorrow or if you have enough on your plate
19 and then we can just figure out another date. Is that fair?

20 SPECIAL MASTER VANASKIE: That's fair. Assuming that
21 I go through these excerpts with the objections, make tentative
22 rulings, and then you confuse me with your arguments.

23 (Laughter.)

24 SPECIAL MASTER VANASKIE: So if I didn't have to
25 listen to your arguments, this would be done pretty quickly.

1 But it's well argued and it makes me reconsider tentative
2 decisions. All right.

3 MR. SLATER: I think what you did today, Judge, really
4 helped, by the way, that each party gets one chance. I
5 think everybody --

6 SPECIAL MASTER VANASKIE: Yes, we'll have to do that.

7 MR. SLATER: I think it's a great way to handle it.

8 SPECIAL MASTER VANASKIE: And with all due respect
9 to -- you know, you're all tremendous lawyers, but sometimes
10 you are making a mountain out of a mole hill. I know
11 that's not going to be well received, but that's the
12 observation that I have.

13 What I'd like to do is take a 15-minute recess and
14 then we'll pick back up with the Teva designations.

15 So, Victoria, are you still there? She'll be back.

16 MS. LOCKARD: Yes, I'm still here.

17 SPECIAL MASTER VANASKIE: Okay. And David, you're
18 still there? We'll --

19 MR. SLATER: I'll shoot him a text to let him know
20 you're ready and find out if he's back yet.

21 SPECIAL MASTER VANASKIE: Yes.

22 (Simultaneous speakers.)

23 THE LAW CLERK: Excuse me, Judge. This is Loretta.

24 SPECIAL MASTER VANASKIE: Yes, Loretta.

25 THE LAW CLERK: I just want to have you clarify what

1 time the hearing will start tomorrow. We weren't sure whether
2 it was 9:30 or 10:00.

3 SPECIAL MASTER VANASKIE: We'll start tomorrow at
4 9:30.

5 THE LAW CLERK: Okay. Thanks.

6 SPECIAL MASTER VANASKIE: Thanks, Loretta. And we are
7 going to take a break now to 3:25.

8 MR. SLATER: Thank you, Judge.

9 MS. ROSE: Thank you, Your Honor.

10 (Brief recess taken from 3:09 p.m. to 3:31 p.m.)

11 SPECIAL MASTER VANASKIE: Hello.

12 MR. STANOCH: Good afternoon, Your Honor.

13 SPECIAL MASTER VANASKIE: Good afternoon. Victoria,
14 are you ready to proceed?

15 MS. LOCKARD: I am. I am here, Your Honor.

16 SPECIAL MASTER VANASKIE: All right. Where did we
17 leave off or where are we picking up?

18 MR. STANOCH: I believe --

19 (Simultaneous speakers.)

20 MS. LOCKARD: Go ahead.

21 MR. STANOCH: I was just going to say I believe we
22 finished Vadsola, subject to a couple issues, and then I think
23 we would be ready to move to Pan Lin, I think.

24 MS. LOCKARD: Well, we -- I went back through -- I
25 wanted to finish Vadsola because I went back through the last

1 section and while a lot of it is subject to the Court's ruling
2 on subsequent remedial measures, there were some individual
3 objections that I wanted to make sure I get heard on. Not
4 every one. Some of them I've passed on.

5 SPECIAL MASTER VANASKIE: All right. So why don't we
6 pick up, so we could complete Mr. Vadsola, with the objections
7 that you would like to pursue, Victoria.

8 MS. LOCKARD: Okay. If we go back to where we
9 stopped, which I believe was -- we started with -- so row 49
10 comes in, row 50 comes in.

11 SPECIAL MASTER VANASKIE: Thank you for that.

12 MS. LOCKARD: And I just wanted to clarify on row 51,
13 I believe the answer continues -- hold on a second. I am
14 sorry.

15 Yeah. So on 52, row 52 is the row that you ruled in
16 Teva's favor on and said it comes out based on lack of personal
17 knowledge.

18 SPECIAL MASTER VANASKIE: Correct.

19 MS. LOCKARD: So I wanted to --

20 MR. STANOCH: I am sorry. Row 52? I thought it was
21 54 we had.

22 MS. LOCKARD: It's page 254, but row 52.

23 SPECIAL MASTER VANASKIE: Row 52 on the spreadsheet,
24 page 254, lines 10 to 21.

25 MS. ROSE: Right. That's where I believe your ruling

1 was that that is out, that you sustained the objection.

2 MR. STANOCH: Yes, I agree.

3 SPECIAL MASTER VANASKIE: Correct.

4 MS. LOCKARD: So the prior row -- the question begins
5 in the prior row, in row 51, so I just wanted to make sure that
6 sustaining the objection applies to the question in row 51 as
7 well.

8 MR. STANOCH: I agree. The answer is out. The
9 question is out. I agree.

10 MS. LOCKARD: All right. Then that covers that.

11 Row 53 as well, same issue. I think the answer just
12 continues on to page 255, line 1, so I assume that's out as
13 well?

14 SPECIAL MASTER VANASKIE: Hold on. And what's your
15 question, Victoria?

16 MS. LOCKARD: So the answer -- because the prior
17 designation was excluded, the answer to the question in the
18 prior designation continues on to line 1 and 2 of page 255. So
19 I think that should come out as well.

20 MR. STANOCH: I thought it was only 254, 4 to 7, the
21 question, I agree, is out per this morning. 254, 10 to 14, the
22 answer is out. I didn't have down that the next question
23 beginning at 254-16 was out. It's a different question.

24 MS. LOCKARD: Okay. Well, that's one I need to
25 clarify because I thought that the Judge ruled that that was

1 out, that that entire designation was out.

2 SPECIAL MASTER VANASKIE: No, I had only ruled up to
3 line 14.

4 So let me look at this: Are you aware of any
5 situation, in your experience as audit hub manager for the APAC
6 region on Teva, ever purchasing product from a vendor that
7 Teva's own audits have found to be not acceptable?

8 The answer was: I don't --

9 (Interruption of transmission.)

10 MS. LOCKARD: ...and the decisions are made, at that
11 point he would have no basis or knowledge for. So it's the
12 same position as the preceding questions, he just doesn't have
13 any personal knowledge. And simply because he prefaced the
14 question with, you know, in your experience as an audit hub
15 manager, it doesn't resolve it because it -- the question
16 implies that as an audit hub manager he should know about
17 vendors, and that misstates the evidence because he doesn't.
18 Vendors and vendor approval is a completely separate department
19 and other witnesses are addressing that.

20 MR. STANOCH: Your Honor, I disagree with that. I
21 disagree with all of the, quote, evidence that Ms. Lockard says
22 what's going to come in and what an audit hub manager should or
23 should not know. If a site's found to be not acceptable, that
24 has a written definition per Teva's own audit reports and
25 guidelines about what that means. And I can certainly ask the

1 audit hub manager what the implication is of an audit finding
2 of not acceptable.

3 SPECIAL MASTER VANASKIE: But his answer is, I don't
4 know.

5 MR. STANOCH: Then, Your Honor, that goes to his
6 credibility that Teva's own audit hub manager, right, who is
7 preparing these audits, right, which it's on -- every one of
8 these audits has a legend about what they're supposed to be in
9 terms of acceptable, conditionally acceptable and not
10 acceptable. And he's telling me and the jury, right, that he
11 doesn't know. I think that's probative of obviously Teva's
12 quality oversight if this person who's supposed to be managing
13 these issues that are supposed to be in black and white, per
14 their SOPs, that he has no idea. That's what he says, if
15 that's even credible.

16 MS. LOCKARD: But the question isn't asking him based
17 on the SOPs, which he is familiar with, should Teva be
18 purchasing a product from a vendor. That I think is a fair
19 question. He can answer based on what he knows from the SOPs
20 or not. This question is asking, in fact, do you know if Teva
21 has ever purchased from a vendor that is not acceptable. And
22 he doesn't know those facts because -- he knows what the policy
23 says but he doesn't know if that's ever happened because he's
24 not in that department.

25 SPECIAL MASTER VANASKIE: Yes, I'll sustain the

1 objection and we won't have that testimony from page 254,
2 line 16 through 255, line 6.

3 MS. LOCKARD: Okay. Thank you.

4 I think the next one -- and I tried to select ones
5 that I thought were worth talking about. If you look --

6 MR. STANOCH: And Your Honor, in the meantime, I'd
7 like a proffer when Ms. Lockard says the evidence is going to
8 show other people are going to talk about that, I'm not aware
9 of any Teva witness who say anything about purchases from
10 vendors who are found to be not acceptable. I'm just putting
11 that on the record. I don't want to fight about it.

12 MS. LOCKARD: Well, I'm saying there are other
13 witnesses who were 30(b)(6) witnesses who were designated on
14 the vendor relations and purchasing, and I'm saying there are
15 other witnesses and you designated their testimony and they
16 were designated as 30(b)(6) witnesses on those topics. So I am
17 not representing that you asked them this exact question, that
18 you did have the opportunity to.

19 SPECIAL MASTER VANASKIE: All right. Let's move on.

20 MS. LOCKARD: Okay. Moving on. So this is a bit of a
21 different issue. If you go down to line 60.

22 SPECIAL MASTER VANASKIE: What page are we on?

23 MS. LOCKARD: Page 266 of the deposition, line 23.
24 I'm sorry, I mean row 60 of the spreadsheet.

25 SPECIAL MASTER VANASKIE: Gotcha. Okay. That helps.

1 MS. LOCKARD: Yeah, sorry. I'm confusing things I
2 realize.

3 SPECIAL MASTER VANASKIE: All right.

4 MS. LOCKARD: Okay. So this is all okay until we get
5 to page 268, line 1.

6 SPECIAL MASTER VANASKIE: Right, okay.

7 MS. LOCKARD: It's referencing Dan Barreto, who's the
8 head of quality, directing that the report should be labeled as
9 privileged and confidential and prepared at the direction of
10 counsel. And then there are questions which I would say are
11 argumentative about well, is he a lawyer, you're not a lawyer,
12 you know. And I think this line of questioning is
13 inappropriate. You know, whether -- we don't know if he was
14 told specifically by an attorney to direct that it was marked
15 privileged and confidential. It wasn't withheld as being such.
16 And it's just argumentative and prejudicial and irrelevant, and
17 the jury just doesn't need to be -- they don't need to be --
18 this testimony does not need to be presented to them. So
19 that's our objection on 268, line 1 forward.

20 SPECIAL MASTER VANASKIE: David?

21 MR. STANOCH: Your Honor, I don't say this lightly.
22 I'm not sure where to begin. Not appropriate for the jury is
23 not a permissible objection. Nothing that Ms. Lockard just
24 said is actually in any of the objections that they had given
25 us in terms of foundation and Rule 407 and calls for a legal

1 conclusion.

2 But putting that aside, putting all of that aside,
3 this is absolutely permissible testimony going to credibility,
4 going to percipient facts of a percipient witness who received
5 the email, who answered all of the questions straightforwardly
6 at the time with no intervening objections at all from counsel,
7 and I don't want to get too far into it, but the judge has not
8 bifurcated liability and punitive damages.

9 I asked this witness, here's an email you're on,
10 yes --

11 SPECIAL MASTER VANASKIE: I understand your argument.
12 I will allow the testimony as it's presented here on page 268
13 of the transcript.

14 MR. STANOCH: Thank you, Judge.

15 SPECIAL MASTER VANASKIE: What's next, Victoria?

16 MS. LOCKARD: All right. Moving on to row 65,
17 page 275, and starting at line 10. It's a similar issue. We
18 did raise relevance. I don't know that this -- well, I know
19 it's not relevant and that's our position. But again, it's
20 asking about, you know, the litigation and did Mr. Barreto ever
21 express to you concern with this report and its impact on
22 litigation, and there's no testimony that it was. The witness
23 just says no, no, no.

24 So a discussion bringing up litigation, similar to our
25 position on the attorney-client privilege instruction, is that

1 it's not relevant. That's the bottom-line objection. It is
2 prejudicial, it is not relevant to the issues, it's not
3 probative of anything in this case, and it's not probative of
4 punitive damages and whether there was egregious conduct here
5 either.

6 SPECIAL MASTER VANASKIE: David?

7 MR. STANOCH: Your Honor, you read this part of the
8 testimony in full, right? It's certainly permissible for us to
9 argue before a jury that Mr. Barreto, of quality, came in
10 after -- this is the gist of what it is. Teva's auditors found
11 ZHP not acceptable for CGMP violations. Mr. Barreto then came
12 in -- and he's never done this before, Mr. Vadsola testifies to
13 that -- told him to change the results from not acceptable to
14 conditionally acceptable. Right? We're entitled to probe why
15 that substantive change about CGMP violations was made. And
16 this is what I'm asking about. But they're saying --

17 SPECIAL MASTER VANASKIE: I agree. I will allow this.

18 MS. LOCKARD: Okay. I assume you're limiting us to
19 one argument per side, same as ZHP right now?

20 SPECIAL MASTER VANASKIE: Yes.

21 MS. LOCKARD: All right. Okay. So moving on to
22 row 66, page 276, line 8, and our objection here is as to 602
23 as well as relevance, 402, and prejudicial, 403. The issue is
24 he's saying -- you know, he's asking about Mr. Barreto's
25 feelings about the report and what did he mean when he said he

1 wasn't pleased, and I think that's outside of Rule 602 because
2 it's really asking him what Mr. Barreto thought or felt. And
3 Mr. Barreto will testify and I'm sure he'll be asked about this
4 as well.

5 SPECIAL MASTER VANASKIE: All right. David?

6 MR. STANOCH: It's the same issue as the last one,
7 Judge. Asking a percipient witness about changes that were
8 made about audit reports and CGMP violations, I asked him how
9 he took an email that he received. That's square within his
10 personal knowledge.

11 If he was on the stand in person, I would be able to
12 ask him these questions. I don't see what the issue is now
13 with the designation.

14 SPECIAL MASTER VANASKIE: I view this one differently,
15 and maybe I was influenced by the witness's answer.

16 The question was: How did you, the witness, take the
17 comment that he was not pleased with the report?

18 And the answer is: I don't know, so I am not prepared
19 on what he meant that he is not pleased with that.

20 I think that's confusing. I'm going to sustain the
21 objection.

22 MS. LOCKARD: The next issue -- and we are getting to
23 the end quickly. But the next one is similar at page 277. The
24 designation starts on line 2. But our objection is at
25 page 278, line 23. And that's where Mr. Stanoch is asking him,

1 and he's reading from the document and he says: He's saying
2 he's starting to wonder if I should classify the audit and its
3 report as unsuitable.

4 That means he's going to do what? Invalidate the
5 audit and the report and make everyone start over?

6 And Mr. Vadsola says: I don't know. He doesn't know
7 what Dan Barreto means.

8 SPECIAL MASTER VANASKIE: Right.

9 MR. STANOCH: Judge, again, Your Honor, he's the audit
10 hub manager in charge of this audit and audit report, he's
11 getting an email saying the audit report may be unsuitable.
12 I'm asking for his personal views and his impression of when he
13 received this email, what that means from an audit hub manager
14 standpoint. He says, I don't know.

15 Just because he says I don't know, I think that's not
16 credible, I think I can present that to a jury. I think if I
17 have an email that he received from his boss where his boss is
18 saying this audit is unsuitable, and I looked at him and said,
19 Mr. Vadsola, what does unsuitable mean, and he goes, I don't
20 know, I think that's permissible testimony.

21 Otherwise, under Ms. Lockard's --

22 SPECIAL MASTER VANASKIE: Yes, the objection is
23 overruled.

24 MS. LOCKARD: Okay. Moving on to page 285, line 9.

25 SPECIAL MASTER VANASKIE: This is row 72.

1 MS. LOCKARD: And again, just for the record, Judge, I
2 haven't objected every time Mr. Vadsola said he doesn't know.

3 SPECIAL MASTER VANASKIE: Right.

4 MS. LOCKARD: So, I mean, there are plenty of examples
5 throughout where there are questions that I think are fairly
6 asked of Mr. Vadsola that is within his realm of core personal
7 knowledge and he says he doesn't know. So I've tried to be
8 selective.

9 But on 285, it's line 11 to 14, as to why Mr. Barreto
10 wanted the audit report to have its conclusion changed. And
11 the witness said: I don't know. He doesn't know why Dan
12 Barreto wanted the conclusion changed. Dan Barreto testified
13 about that in his deposition. Again, I'm sure he's going to
14 testify at trial.

15 SPECIAL MASTER VANASKIE: Yes, it just seems to me,
16 David, that you could have asked the question did Barreto tell
17 you why he changed the conclusion. The question, do you know
18 why, that does call for speculation.

19 MR. STANOCH: He either knows or he doesn't, Judge,
20 respectfully. And he testified earlier in this whole area, and
21 obviously Ms. Lockard doesn't like the sizzley bits here that
22 we have of Mr. Barreto changing what his own audit team did,
23 and I understand that, why they're coming back to all of these
24 questions. Mr. Vadsola, a few pages earlier, testified that he
25 had conversations with Mr. Barreto and he couldn't quite

1 remember what they talked about, about this very audit report
2 and instance. So I'm coming back here and saying, did he tell
3 you or did you know? That's distinguishing without difference.
4 Because if he was told, he'd know or not. Right? Yes or no?
5 Does he know, yes.

6 SPECIAL MASTER VANASKIE: We could find out different
7 ways.

8 MR. STANOCH: Because --

9 SPECIAL MASTER VANASKIE: I will sustain the
10 objection.

11 What's the next one, Victoria?

12 MS. LOCKARD: Okay. Let's go to page 288, line 4.

13 And we had objected to this based on 402, 407, and our
14 objection was overruled. So if that's coming in, we want to
15 add the counter of 287-16 to 188-3.

16 SPECIAL MASTER VANASKIE: All right. Let me look at
17 it.

18 All right. And your position, David?

19 MR. STANOCH: It's the first I'm hearing of this
20 counter, Your Honor. So in looking at it, I don't see what the
21 completeness is for the surrounding testimony. The actual
22 designation was, right, that Mr. Barreto and Mr. Hatt were not
23 part of the audit team that actually audited ZHP, correct; they
24 did not make observation, correct; et cetera. So I'm not sure
25 what the completeness claim is here.

1 MS. LOCKARD: Well, they cut out part of the answer
2 clarifying why Barreto and Hatt are part of the audit group.
3 And I think that it needs to be made clear because the way that
4 it's clipped it suggests that they're not part of the audit
5 team at all. And we simply want to include benign testimony
6 that says, well, they are part of the audit team. And then
7 Mr. Stanoch can say, yeah --

8 SPECIAL MASTER VANASKIE: I will allow it.

9 MS. LOCKARD: So I think the very last two are at
10 row 84 and 85, page 301 and 302.

11 SPECIAL MASTER VANASKIE: Say that again.

12 MS. LOCKARD: It's row 84, page 301 --

13 SPECIAL MASTER VANASKIE: Okay. I'm with you now.

14 MS. LOCKARD: So I just -- and your ruling may be the
15 same. But this is a different audit, okay, starting with this
16 designation on page 301. Now we're talking about the audit of
17 the facility a year later. This is in 2019. This is after
18 Teva stopped manufacturing any valsartan, it's after all of the
19 Teva's internal discussions about what to do with the ongoing
20 ZHP issues. And this, aside from being -- you know, it's not a
21 subsequent remedial measure based on your prior ruling, but
22 it's still irrelevant because it's so far off in time, it's
23 related to an audit -- and this facility is not even producing
24 valsartan API for Teva any more, and we think there has to be a
25 line drawn somewhere. I mean, based on the judge's ruling, it

1 was clear not every audit is going to be relevant and there has
2 to be some that aren't. This is not one of those that is
3 relevant, it's far past the time of the relevant time period
4 here, and it's going to be introduced to suggest that Teva, you
5 know, shouldn't have rated ZHP conditionally accessible. And,
6 you know, it's basically criticizing Teva over a facility
7 rating for a facility they're not even purchasing any product
8 from.

9 So the argument there applies to this designation as
10 well as the designation following on page 302. Hold on. Let
11 me get there.

12 But anything to do with the 2019 audit, we have a
13 separate independent relevance objection to that audit as well.

14 SPECIAL MASTER VANASKIE: So the question here is, as
15 of May 2020 -- am I on the right spot, page 301, line 22? I
16 think as of May 2020, Teva's recording audits of ZHP have found
17 the site acceptable, but the FDA import ban on ZHP was still in
18 effect. Does that sound right to you?

19 He says: Correct.

20 And then: Okay. So even though Teva's own auditing
21 of ZHP ultimately resulted in Teva believing the site was
22 acceptable, the FDA was still not letting companies use ZHP
23 product in their pharmaceutical drugs sold in the U.S.?

24 The witness answered: I don't know.

25 Then you go on: Well, if there's an FDA import ban in

1 place on ZHP, could Teva use ZHP API in its products that were
2 being sold in the United States?

3 Answer: In general, if any supplier receives the
4 import alert, they're not able to supply any material to USA.
5 During the whole process, the end user of the API material and
6 the vendor, they need to notify them and they need to ensure
7 that they are not supplying this material to U.S. market.
8 That's correct.

9 So what's the issue here?

10 MS. LOCKARD: Well, the one issue relates -- just
11 prior to this in the deposition testimony, he's saying -- he's
12 asking the witness about this 2019 audit and he's questioning
13 the witness about the 2019 audit. So we have a couple of
14 objections.

15 The one is that testimony about the 2019 audit -- and
16 he's sort of comparing what the conclusions of the 2019 audit
17 were versus the import ban. And we think any discussion about
18 the findings of the 2019 audit should be excluded because
19 they're irrelevant. That's one argument.

20 The second argument, which we've also included 602 as
21 to personal knowledge, is that Mr. Vadsola doesn't know what
22 FDA is doing with the import ban. And so there are these
23 questions asking him as well about the import ban and what FDA
24 is doing, he doesn't know.

25 He says on line 6, this is bleeding towards the end,

1 that even though Teva's on auditing of ZHP -- meaning in
2 2019 -- ultimately resulting in Teva believing the site was
3 acceptable, the FDA was still not letting companies use the ZHP
4 product in their pharmaceutical drugs.

5 And he says: I don't know.

6 Because he doesn't know what FDA is doing vis-a-vis
7 ZHP and the import ban.

8 So the audit, the discussion of the audit in 2019 is
9 irrelevant. He doesn't have personal knowledge about the
10 import ban. So --

11 SPECIAL MASTER VANASKIE: All right.

12 MS. LOCKARD: -- those are the objections.

13 SPECIAL MASTER VANASKIE: David?

14 MR. STANOCH: Thank you, Your Honor.

15 In terms of relevance, I think we've addressed this ad
16 nauseam. We're not even going into detail here on this
17 specific audit. Right? Clearly we're showing with this line
18 of questioning, Judge, that Teva's ratings of acceptable, all
19 right, are very loose, and are done improperly and that they're
20 saying a supplier is acceptable even though there's situations
21 when, for example, the FDA says you can't sell the product.
22 And that undermines the credibility and the robustness of when
23 Teva witnesses, when they put their own witnesses on say, oh,
24 well, we do audits and we find them acceptable.

25 And then I want to cross, and I'm allowed to put on

1 evidence to countervail that, to say your acceptable ratings
2 are not up to snuff and are a sham, and I mean that
3 colloquially.

4 In terms of the other issue of 602, I must be reading
5 something different, Judge. He says -- I ask the question that
6 he says "correct" to my first question. He knows. It's within
7 his personal knowledge. And then --

8 SPECIAL MASTER VANASKIE: No, I will allow this
9 testimony. The objection is overruled.

10 MR. STANOCH: Thank you, Judge.

11 SPECIAL MASTER VANASKIE: Is that it, Victoria?

12 MS. LOCKARD: That's it for Vadsola for plaintiffs'
13 designations.

14 SPECIAL MASTER VANASKIE: All right. Can we go to Pan
15 Lin now?

16 MS. LOCKARD: Yes. I'll pull that up.

17 SPECIAL MASTER VANASKIE: I'll pull up the
18 spreadsheet.

19 MS. LOCKARD: And this witness was two days, so there
20 is a tab for each day, I believe.

21 SPECIAL MASTER VANASKIE: Yes, I believe that's true.
22 And we're starting on May 26th, the first day of the
23 deposition.

24 MS. LOCKARD: Correct. Okay. I have it in front of
25 me.

1 SPECIAL MASTER VANASKIE: All right.

2 MS. LOCKARD: The objection here related to the 2015
3 audit. So this is concerning the Zhengzhou facility. And if
4 your ruling stands for Vadsola, I think that would apply for
5 this first one.

6 MR. STANOCH: Yes, I agree.

7 SPECIAL MASTER VANASKIE: All right.

8 MS. LOCKARD: Second, next row --

9 SPECIAL MASTER VANASKIE: Page 57 of the deposition.

10 MS. LOCKARD: Right, page 57.

11 SPECIAL MASTER VANASKIE: Line 20.

12 MS. LOCKARD: So this is one where I had said -- you
13 know, we were standing on the objection, but if this comes in
14 we also wanted to add a counter of 56-8 to 56-14 and 59-20 to
15 61, where Mr. Lin essentially explains that this is a different
16 facility.

17 SPECIAL MASTER VANASKIE: All right. And your
18 position, David?

19 MR. STANOCH: I'm hearing these counters for the first
20 time, Your Honor, so I'm trying to look through it. Mr. Lin, I
21 think, it's not necessary for completeness. He's not even
22 sure.

23 If we go back to this "I don't know" or if someone
24 lacks personal knowledge, it shouldn't come in standard. He
25 says, I'm not entirely sure, I'm not entirely sure whether

1 they're the same or not. So he begins by saying they're a
2 different facility in this counter that Ms. Lockard is
3 proposing.

4 But then in that very same answer he goes on, right,
5 at 56-10, 11, 12, 13, 14: So they're different; and maybe
6 they're different products, I'm not sure; I'm not entirely sure
7 whether they're the same or not. Right? So he doesn't even
8 know.

9 So I would say that anything they're trying to -- they
10 have other witnesses, Judge, who can say that this is a
11 different facility that was making different valsartan finished
12 dose versus API. Either way, Teva was auditing it and we went
13 through the audit report earlier today. So I would say that
14 that counter is not necessary for that reason.

15 And I didn't quite catch the other counter that she
16 mentioned.

17 MS. LOCKARD: So the other counter -- and if I may
18 just be heard a second on this?

19 MR. STANOCH: Are we going back and forth again?

20 MS. LOCKARD: No. This is important, though.

21 Because the first counter I included for plaintiffs'
22 benefit. I'm happy not to include that one. But for fairness,
23 I included it, because the second counter is where he says,
24 Okay, I would like to make a supplement here regarding the
25 previous questions." And he says, That report was concerning

1 another ZHP facility. That was separate from the Chuannan
2 facility. I want to make that supplement.

3 So I'm fine leaving in the second counter, but I
4 thought plaintiffs would complain if we didn't include the
5 first one where he said he didn't know.

6 So does that make sense, Judge?

7 SPECIAL MASTER VANASKIE: Somewhat. I certainly would
8 allow in the counter-designation on page 59 from line 18
9 through 24, which makes clear that the report he was being
10 asked about concerned a different ZHP facility. And I think in
11 fairness, the other counter-designation you made should come in
12 as well.

13 MS. LOCKARD: So it was 56-8 to 56-14 that we asked
14 for and 59-20 to 61. So those should both come in.

15 SPECIAL MASTER VANASKIE: Those should both come in.
16 All right?

17 MS. LOCKARD: All right. That takes us to page 60,
18 line 13. And this -- the objection was based on relevance to
19 the Zhengzhou facility audit, so I think we have a ruling on
20 that.

21 The next one would be --

22 SPECIAL MASTER VANASKIE: Hold on. Let me make sure
23 we're all on the same page here.

24 So on page 60, lines 13 to 16, it's just a preliminary
25 question: I'd like to ask you some questions about your

1 preparation for the May 2018 audit of ZHP you conducted. Okay?

2 Okay.

3 Then what?

4 MR. STANOCH: Your Honor, I think Ms. Lockard was
5 saying that even though they had objected to that, because Your
6 Honor ruled this morning with Mr. Vadsola about this same fall
7 2018 audit report, that there's no longer an issue. She can
8 correct me if I'm wrong.

9 SPECIAL MASTER VANASKIE: Okay.

10 Is that right, Victoria?

11 MS. LOCKARD: That was what's in my notes, but it is
12 confusing that it talks about -- it's directing him to the
13 May 2018 audit, which is not the one that we objected to. So I
14 think that is okay.

15 SPECIAL MASTER VANASKIE: All right. Let's assume for
16 now that it is okay. If you go back and look at it again and
17 want to reassert the matter, you're certainly free to do so.
18 So you're not prejudiced.

19 MS. LOCKARD: Okay.

20 SPECIAL MASTER VANASKIE: So does this take us now to
21 page 62, line 18?

22 MS. LOCKARD: Yes, 62-18 to 21.

23 SPECIAL MASTER VANASKIE: Then we go, for completeness
24 purposes, to 63, line 13?

25 MS. LOCKARD: Right. So plaintiff objected to our

1 counters. I think he is up first.

2 SPECIAL MASTER VANASKIE: Yes.

3 MR. STANOCH: Quite simply, Your Honor, the actual
4 designation, page 62, 18 to 21, is simply by reference of the
5 document.

6 It looks like you, you, were communicating with ZHP in
7 the fall of 2017 in preparation for the May 2018 audit, right?

8 Yes.

9 Thank you. You can put that aside -- that exhibit.

10 Right? So that was finishing the questioning about
11 that exhibit. Right?

12 Then the proposed counters comes in with some muddled
13 testimony about him saying about who was communicating with
14 ZHP.

15 He says: There's many products, I'm not sure whether
16 my colleagues were communicating. It involves many products,
17 maybe more than ten products. Which doesn't really speak to
18 who's communicating.

19 So I don't see how -- and this might be a translation
20 issue because this witness, even though he writes and speaks in
21 English, he had a translator. I don't know if that was part of
22 the problem with these counters at 63, 13-18 and 64, 4
23 through 11, but I just don't see how that has anything to do
24 with, quote, completeness when I was asking him about what he
25 was doing in the fall of 2017 with a reference to a document.

1 MS. LOCKARD: So the first, the question designated by
2 the plaintiffs was saying: Were you the one communicating with
3 ZHP in the fall of 2017 in preparation for the May 2018 audit,
4 in preparation for, and he says "yes."

5 And then the question we want to include is simply:
6 Who was responsible for communicating with ZHP for the May 2018
7 audit?

8 SPECIAL MASTER VANASKIE: Yes, I think it's allowable.

9 MS. LOCKARD: It's just a time reference?

10 SPECIAL MASTER VANASKIE: Yeah. So 63, line 13 to 63,
11 line 18; 64, line 4 to 64, line 11, that all comes in.

12 MS. LOCKARD: Okay. So going to page 66, line 13, I
13 think is the next dispute.

14 SPECIAL MASTER VANASKIE: Yes.

15 MS. LOCKARD: And we had objections, but withdrew
16 them, and then counsel is objecting to our completeness
17 counters.

18 SPECIAL MASTER VANASKIE: And they're at 68, line 10
19 to line 12?

20 68, line 10 to 12: Question: Do you recall auditing
21 valsartan?

22 Answer: I don't think I did that.

23 And then 68-20: Do you recall if you wrote any
24 sections of this audit report that related to valsartan?

25 Answer: I want to get a clarification from you

1 regarding your question. Are you asking me whether I audited
2 this report or what exactly are you asking me?

3 I was asking, sir, whether you were responsible for
4 writing any part of this report that related to valsartan.

5 Answer: I don't think I wrote anything related to
6 valsartan here. However, after the May 2018 audit, I did audit
7 matters related to valsartan later on and I do remember that
8 clearly.

9 And that's what you want to put in, Victoria?

10 MS. LOCKARD: Correct, Your Honor, because he's asking
11 Mr. Lin were you on site at the ZHP facility for the entirety
12 of the audit and he's asking about the scope of the products
13 and it says valsartan is listed within the scope.

14 So then we wanted to just clarify that Mr. Pan Lin did
15 not audit valsartan and that he did not write any sections of
16 the audit report related to valsartan. So I think it's just a
17 clarification to provide some context for this jury as to what
18 Mr. Lin was doing and what his relationship with this audit
19 report is.

20 SPECIAL MASTER VANASKIE: Yes. I think that's
21 permissible. I'll allow it.

22 MS. LOCKARD: I think the next is we go to page 72.

23 SPECIAL MASTER VANASKIE: You want to put in --
24 there's no objection to what has been designated by the
25 plaintiff, but the plaintiff has objected to your

1 counter-designation on page 72, lines 1 to 8.

2 MR. STANOCH: That's right, Your Honor, because 72, 1
3 through 8 is not relating to my designation beginning at 72-9.
4 Right? 72-9 is talking about the Workshop 12 --

5 SPECIAL MASTER VANASKIE: No, but I think it's --

6 MR. STANOCH: And then right before that he's saying
7 he didn't -- I am sorry.

8 If you look at 71, it's saying: Do you see a
9 reference to USDMF grade?

10 And he says: I can't say so. When it's written US,
11 I'm not entirely sure what that means.

12 And then I say: You didn't write that section, did
13 you?

14 And he says: I don't think I did.

15 Stop.

16 And then I move on to another reference about Workshop
17 12.

18 So when he's saying "I didn't write this section,"
19 he's talking about the section that I did not designate about
20 USDMF, right? He's not talking about what they're trying to
21 throw in. That would be misleading. He's saying he didn't
22 write the section about USDMF grade on page 71, not on what I
23 asked him later about the maintenance on page 72.

24 MS. LOCKARD: So I think we can -- I think this was a
25 holdover from where the designation was broader and then was

1 cut back, so I think we can drop lines 1 to 4 about "you didn't
2 write this section" because I think Mr. Stanoch is right that
3 that's referencing a section of testimony that was taken out.

4 SPECIAL MASTER VANASKIE: Okay.

5 MR. STANOCH: 1 through 8, right? Because then the
6 next question is -- I'm clarifying what he just said in 1
7 through 4 and he says "yes."

8 So the entire counter I think would come out, 72, 1
9 through 8.

10 MS. LOCKARD: Well, but he did not -- the second part
11 of that designation is broader because he did not do the audit
12 of the valsartan product. So he did not do the audit of the
13 valsartan product, which is important. He was not the one --

14 MR. STANOCH: Oh, you already got that in. Judge
15 Vanaskie allowed that a moment ago. And now that was a
16 clarifying question to a completeness designation, which you've
17 agreed should not come in, so I don't think that should come
18 in. Otherwise, then it should come in because now it's
19 cumulative testimony about he didn't -- he doesn't think he
20 audited the valsartan product.

21 MS. LOCKARD: He said he didn't recall -- he did not
22 write any of the sections of the audit report that relate to
23 valsartan.

24 He said: Do you recall auditing valsartan?

25 MR. STANOCH: This is a completeness objection, Judge.

1 They want -- I have a question designated right below talking
2 about Workshop 12 and they want to put in --

3 MS. LOCKARD: I'll withdraw all of it.

4 SPECIAL MASTER VANASKIE: All right.

5 MS. LOCKARD: I'll withdraw all of it. I think we
6 have in earlier that he did not do the audit of valsartan.
7 Okay. That's fair.

8 SPECIAL MASTER VANASKIE: All right. It's out.

9 MS. LOCKARD: 98.

10 SPECIAL MASTER VANASKIE: You're up to 98 or 72?

11 MS. LOCKARD: Oh, did I skip one?

12 SPECIAL MASTER VANASKIE: No, I don't think so. I
13 think you're right. We're up to 98.

14 MS. LOCKARD: I just want to make sure --

15 SPECIAL MASTER VANASKIE: Yes, you can take your time.

16 MS. LOCKARD: It's getting late and my contacts are
17 glued to my eyeballs right now.

18 Okay. So 98, yeah, we had objections to this as based
19 on relevance and prejudicial. This seems to be ZHP's reply
20 that he's reading from. This is not a Teva conclusion or
21 showing Teva's knowledge. He's asking an interpretation of
22 what ZHP wrote.

23 So we object to its misleading, it's -- you know, 602,
24 it lacks personal knowledge. And it's prejudicial on top
25 because it's using the term "highly toxic," which is not

1 language that Teva used.

2 MR. STANOCH: May I, Your Honor?

3 SPECIAL MASTER VANASKIE: Yes, you may, David.

4 MR. STANOCH: Again, I'm not faulting her, this is a
5 fluid process, but, again, the only objection we had here was
6 speculation. So I'm hearing a laundry list, so I'll try to
7 deal with it all.

8 This isn't a ZHP document. I'm asking this witness,
9 the Teva auditor who went to ZHP on May 2018 about the Teva
10 audit report which has a discussion in it back and forth in
11 writing with ZHP about certain issues. So he's not speculating
12 about anything. He was an audit member who was there, I'm
13 asking about the audit report that he's named on, about
14 information that they wrote down in their own audit report
15 about when they were auditing ZHP.

16 So this is -- there's nothing prejudicial or
17 misleading and the document, you know, shows that. This is the
18 back and forth that Teva recorded in its own documents about
19 what it was finding at ZHP and what ZHP was telling it. That's
20 permissible testimony and evidence, Judge.

21 SPECIAL MASTER VANASKIE: Yes, I will allow it. That
22 takes us down to page 100, line 1, which is a continuation.
23 This is a counter-designation at page 100, lines 4 to 7.

24 MS. LOCKARD: Okay. So we were at 98-12.

25 SPECIAL MASTER VANASKIE: Right.

1 MS. LOCKARD: And then there was 98-20.

2 SPECIAL MASTER VANASKIE: Right.

3 MS. LOCKARD: And I guess that's the answer because
4 he's saying this section was written by ZHP, not Teva.

5 SPECIAL MASTER VANASKIE: Right.

6 MS. LOCKARD: But that goes to the same. Okay. And
7 then 99-1 --

8 SPECIAL MASTER VANASKIE: Through 24. I'm saying all
9 of that comes in.

10 MS. LOCKARD: All of that, okay.

11 SPECIAL MASTER VANASKIE: Yes.

12 MS. LOCKARD: Okay. So then 100, you're right, at 1
13 through 3, then we wanted the completeness counter for 100, 4
14 to 7, and they objected.

15 SPECIAL MASTER VANASKIE: Yes. And I think it's
16 appropriate, I think it is continuation of the examination and
17 we'll allow it.

18 MR. STANOCH: Understood, Judge.

19 SPECIAL MASTER VANASKIE: Then you have page 103,
20 line 8 to 14; and then 103, 17 to 18 as for completeness
21 purposes, and I will allow it.

22 MR. STANOCH: Your Honor, understood. But if 17 and
23 18 is coming in, I'd ask that 103, 19 through 104 come in as
24 well because it's all talking about clarification. Right? I
25 first asked him a question, the report says -- did it say

1 anything was incomplete? He said no.

2 They're not having in -- he adds here, he does not
3 specifically clarify.

4 And then I asked: Does it indicate any item was
5 complete?

6 He says: I can't put it that way.

7 And I say: Right, because it says "reviewed," not
8 complete.

9 Yes, it was how it was written.

10 I think all of that should come in then.

11 MS. LOCKARD: I'm fine with that. I don't think it
12 really answers the question, but I have no objection to that.

13 SPECIAL MASTER VANASKIE: Yes, I think it all comes
14 in.

15 MR. STANOCH: Thank you.

16 MS. LOCKARD: 105-5?

17 SPECIAL MASTER VANASKIE: That's what I have.

18 MR. STANOCH: Same.

19 SPECIAL MASTER VANASKIE: They designated 105-13 to
20 16.

21 MR. STANOCH: Right. And, Your Honor, the point is,
22 I'm just establishing what the document is and then move on to
23 have questions for him. Right? And they want to throw in that
24 he wasn't part of the audit team for the specific 2015 audit.

25 I don't see how that's really complete because, you

1 know, the SOPs are going to say that auditors should look at
2 the issues when they do go to audit, which he admits he did in
3 May of 2018, should look at the issues from the last audit.

4 So I know they want to put in how he wasn't part of
5 the team, but I don't think that's really pertinent to be left
6 to --

7 SPECIAL MASTER VANASKIE: I think it is pertinent.
8 You could be left with the wrong impression that he was part of
9 the team in 2015, so --

10 MR. STANOCH: Understood.

11 SPECIAL MASTER VANASKIE: -- I will allow it.

12 Are we up to page 118 now or --

13 MS. LOCKARD: Yes.

14 MR. STANOCH: I think so.

15 SPECIAL MASTER VANASKIE: Row 14 of the spreadsheet.

16 MS. LOCKARD: Right.

17 MR. STANOCH: And this is a Teva completeness issue, I
18 believe, Judge?

19 SPECIAL MASTER VANASKIE: Yes.

20 MR. STANOCH: And here again, I'm asking Mr. Pan Lin
21 if he recalled any conversations about potential nitrosamine
22 impurities when he was on the ground at ZHP's facility in
23 May 2018, just a few weeks before all the recalls broke. And
24 he says, no, we didn't talk about that.

25 I don't see for completeness purposes -- I don't see

1 what's misleading about that. They either did or they didn't,
2 and he clearly says, no, we did not.

3 And then what he tries to inject and the question they
4 want to include is, well, because at the time no one really
5 knew about NDMA, so we wouldn't talk about it because nobody
6 really knew about it. It's simply, did you talk about
7 something, yes, no. He says no. There's no need for him to --
8 again, personal knowledge -- I don't know his personal
9 knowledge about what he starts talking about the timing and who
10 knew what and when and I just don't think it's necessary.

11 MS. LOCKARD: So, Your Honor, this is -- it is
12 misleading and prejudicial because the question is asking at
13 the time in May, did you talk about nitrosamines. Well, the
14 whole underlying defense or part of it is that nobody was
15 talking about nitrosamines at that time except Novartis, I
16 guess, which we weren't -- Teva wasn't told about.

17 But it suggests that somehow they just omitted it or
18 they were sloppy and they didn't bring it up. Nobody at Teva
19 had seen the word "nitrosamine" in relationship to this
20 valsartan API at that time. So he should be entitled to give
21 an explanation for that answer. Because if he were on the
22 stand and he was asked this question, he would absolutely
23 include that explanation. No, we didn't because, and here's
24 why. Nobody --

25 SPECIAL MASTER VANASKIE: Yes, I will allow it.

1 MS. LOCKARD: Sorry, I think I just got a little extra
2 kick from my coffee -- my lunchtime coffee, if I'm getting
3 loud.

4 (Laughter.)

5 SPECIAL MASTER VANASKIE: Now are we up to page 120,
6 row 15?

7 MR. STANOCH: Yes.

8 SPECIAL MASTER VANASKIE: And the objection is to the
9 designation, 120, lines 3 to 7.

10 MR. STANOCH: Again, I'm asking him if he knows if ZHP
11 ever told Teva something. Counsel says he can answer if he
12 knows. He asks me for clarification about -- the witness says,
13 are you talking about 2017?

14 I say, yes.

15 He says, I don't know.

16 MS. LOCKARD: So this is -- again, this is another --
17 we made the speculation argument, it's a personal knowledge
18 argument because he's not a 30(b)(6) witness and to ask him
19 what did Teva as a whole know or did anybody at Teva get told
20 about this is unfair when this witness doesn't have personal
21 knowledge and he wasn't designated as 30(b)(6) on this.

22 And our testimony from other witnesses who are
23 knowledgeable will clearly be no, we did not know about that
24 beforehand. But this witness, it leaves open the possibility
25 that maybe we did because he doesn't know. But he only sees a

1 small slice of the audit piece. So again, it's outside his
2 personal knowledge.

3 SPECIAL MASTER VANASKIE: I'm having trouble following
4 this.

5 MR. STANOCH: Your Honor, every question to a witness
6 is going to be obviously to the extent of his personal
7 knowledge. This -- and I'm not going back rearguing things
8 from this morning, earlier today, but this suggestion that I
9 have to preface every question "to your knowledge do you know
10 if ZHP ever did something" or "to your knowledge do you know if
11 the sky is blue" or "to your knowledge do you know if your
12 employer received any information from ZHP." Right? I don't
13 have to preface every question like that. Right?

14 I'm able to ask him a question, which his counsel at
15 the time said "answer if you know." Right? If he knows
16 something. He either does or he doesn't. And he said he
17 didn't. And it's pertinent because this person has been an
18 auditor of ZHP for something like ten years, a Teva auditor
19 who's been going to ZHP repeatedly over and over again.

20 MS. LOCKARD: You don't have to preface it with that
21 kind of language every time, but you do have to ask questions
22 that are within the personal knowledge. And you can establish
23 that by seeking a foundational question, which wasn't asked.

24 Here it is prejudicial and unfair because the
25 discussions about the disclosure of the nitrosamines didn't

1 come through the audit function. It came through other
2 channels. So this witness would not have known what other
3 departments or channels at Teva knew or what they were told
4 about ZHP and their nitrosamine.

5 MR. STANOCH: Even if he would. And he said he
6 didn't. He could have said yes, and then I'm entitled to get
7 that information. And prejudicial, that's not an --

8 (Simultaneous speakers.)

9 SPECIAL MASTER VANASKIE: Here's what I'm having
10 trouble with. We have questions and then objections and then
11 clarifications. So let's focus in on what is the question and
12 what is the answer at issue here.

13 I'm looking at page 120, lines 3 to line 7. The
14 objection is it's not necessary for completeness -- no,
15 speculation. 120, lines 3 to line 7.

16 Question: Did ZHP ever tell Teva that ZHP had
17 discovered, as early as July 2017, that nitrosamine impurities
18 could form from the sodium as a quenching during the
19 manufacture of valsartan API?

20 Answer: Are you talking about 2017?

21 Question: Yes.

22 Answer: I don't know.

23 Is that what you're trying to present here?

24 MS. LOCKARD: That's what plaintiffs are trying to
25 present and that's what we're objecting to. And the

1 speculation objection is the same as -- it is a personal
2 knowledge objection.

3 Because again, if this were a 30(b)(6) witness, this
4 would be a perfectly appropriate question. But he's asking
5 what Teva broadly as a company knew, and that is outside of
6 this witness's personal knowledge.

7 So he can ask -- you know, he can certainly ask if he
8 was ever privy to any disclosure of that. And even the way
9 it's asked, if the witness had said, oh, yes, I do know, then
10 he has an argument that he's laid the foundation for some
11 personal knowledge because the witness has admitted he has
12 personal knowledge.

13 But he's saying he doesn't know because he doesn't
14 have any personal knowledge. He can't tell you whether or not
15 Teva heard about this before or after because he's not a
16 30(b)(6) witness and he doesn't have that knowledge as somebody
17 in China just dealing with the local audit.

18 So that's why we think it's an unfair question,
19 inappropriate, and he doesn't have the personal knowledge to be
20 able to answer it or to be able to respond on behalf of Teva as
21 a whole.

22 SPECIAL MASTER VANASKIE: All right. So looking at
23 row 15 of the spreadsheet, I will sustain the objection. I
24 will also sustain the objection at row 16.

25 And, therefore, the counter-designation at 119,

1 line 23 to 120, line 1 should come out as well. All right?

2 MR. STANOCH: Understood, Judge.

3 MS. LOCKARD: I'm with you.

4 SPECIAL MASTER VANASKIE: So that takes us to row 17.

5 MS. LOCKARD: And there was no objection, but
6 plaintiffs objected to our counter.

7 SPECIAL MASTER VANASKIE: That's at 123, line 22. And
8 I will allow the counter to come in.

9 MR. STANOCH: Understood, Judge.

10 SPECIAL MASTER VANASKIE: Next we're at row 18.

11 Page 126, lines 18 to 22.

12 MS. LOCKARD: We actually withdrew our objection to
13 this one.

14 SPECIAL MASTER VANASKIE: Okay. Good. So that's it.
15 The spreadsheet I have in front of me doesn't show that.

16 MR. STANOCH: Sorry, Judge, I guess --

17 SPECIAL MASTER VANASKIE: That's okay.

18 So now we're at row 19, deposition page 128, lines 6
19 to 17.

20 MS. LOCKARD: Again, this is -- we withdrew our
21 objection from this. I think we were contemplating adding in
22 the subsequent remedial measures to this, but we understand
23 your rulings. I don't think there's anything to --

24 SPECIAL MASTER VANASKIE: Okay. Good. Let's go to
25 row 20 then. The testimony at page 129, lines 5 to 20.

1 MS. LOCKARD: I'm looking at my notes.

2 SPECIAL MASTER VANASKIE: All right.

3 MS. LOCKARD: Yes, I think we -- so we had objected to
4 this because we believe it misstates the testimony, it's
5 argumentative, and it's not relevant. It's really kind of
6 confusing and unhelpful to the jury. I really -- I don't think
7 the two witnesses were really communicating.

8 SPECIAL MASTER VANASKIE: Let me look at the
9 contingent counter on the next page.

10 MR. STANOCH: Judge, if she withdraws the objections,
11 I'll agree to the contingent counter.

12 SPECIAL MASTER VANASKIE: So let me see if I
13 understand this.

14 Okay. So you're saying have admitted the testimony
15 and questioning from 129, line 5 through 20; and then 129-23
16 and 24; and 130, lines 2 to 5; and 130, lines 8 to 11?

17 MR. STANOCH: Yes.

18 SPECIAL MASTER VANASKIE: Victoria?

19 MS. LOCKARD: That's agreeable.

20 SPECIAL MASTER VANASKIE: Okay. Yes, I think that
21 makes it clearer.

22 So now we're up to row 22. 131, lines 5 to 8.

23 MS. LOCKARD: Okay. Let me get there. I think I said
24 I withdraw that objection to that question and answer if you
25 would take out the last question and answer which we just

1 agreed could come in.

2 SPECIAL MASTER VANASKIE: You're losing me, Victoria.

3 MR. STANOCH: You're losing me too.

4 MS. LOCKARD: Yeah.

5 SPECIAL MASTER VANASKIE: I know this is hard thought.

6 MS. LOCKARD: We had proposed in negotiation where we
7 would withdraw our objection if they took out the prior
8 question and answer, and you just ruled on that. I think this
9 is okay. Let me just look very quickly.

10 So we're talking about would it be acceptable for an
11 API supplier such as ZHP to withhold information.

12 And he says: Yes, I cannot speculate on that when I
13 received a notification or, in fact, I did not receive a
14 notification directly. Rather, I received a notification from
15 my superior department.

16 And so that part I was okay with, but it's the -- the
17 objection about "Why, Mr. Pan, are you trying to protect ZHP?"
18 That's what I really had an objection to. The rest of it was
19 fine.

20 SPECIAL MASTER VANASKIE: Yes, I'll sustain that.

21 MS. LOCKARD: Okay. So that takes us to --

22 MR. STANOCH: That's it.

23 SPECIAL MASTER VANASKIE: That's it, right?

24 MR. STANOCH: It was the question and answer --

25 MS. LOCKARD: Okay. That's it for that page. So that

1 takes us to page second, I think -- second day.

2 SPECIAL MASTER VANASKIE: Second day.

3 MR. STANOCH: There's only eight rows, Judge.

4 MS. LOCKARD: Yes, there's only eight, so we could get
5 through this, I think.

6 SPECIAL MASTER VANASKIE: Okay.

7 MS. LOCKARD: Then we'll be done.

8 SPECIAL MASTER VANASKIE: That would be good.

9 MR. STANOCH: Thank you, Judge.

10 And I think the first two are completeness. And I'll
11 just allow Your Honor to reacclimate with these pages of the
12 Day 2 transcript and then --

13 SPECIAL MASTER VANASKIE: Let me get the Day 2
14 transcript in front of me. I have it now.

15 Okay. So plaintiff has a designation on 152, line 10
16 to 152, line 21.

17 MR. STANOCH: Correct. And the question is simply
18 about audits and said -- right, about -- yes, about the purpose
19 of the Teva audit is to ensure that an API of the supplier is
20 complying. And he says "yes" and he explains. That's it.

21 And then the next -- all the other questions for
22 pages, it looks like, the defendants want for quote/unquote
23 completeness, are about other things. They're about what else
24 they might do besides audits. But then he answers, oh, well,
25 we place a high value on audits, which is not even responsive.

1 And then he talks about official regulatory audits,
2 which was nothing about the purpose of the Teva audit. And
3 then they want more and more pages -- and Your Honor can read
4 it. I just don't think the next five pages of
5 counter-designations are a fair and balanced way of completing
6 the simple question and answer, which was simply what do you do
7 a Teva audit of an API supplier for, and he fully answers it.

8 MS. LOCKARD: Well, Your Honor, it's not five pages
9 worth. I mean, there are five --

10 MR. STANOCH: Five separate counters. I apologize.

11 MS. LOCKARD: Five separate counters. And we think
12 that they are -- they do provide completeness to the question,
13 which is he's asking how does Teva ensure that an API supplier
14 is compliant with CGMPs.

15 So he is talking about regulatory activity and
16 regulatory audits. That is one of the ways that they ensure
17 that their supplier is compliant. I mean, they do their own
18 audits, yes. But an important part of that, he would explain
19 at trial on the stand, is that also the FDA does their audits,
20 and ZHP is supposed to provide that information back to Teva.

21 So it's artificially limiting the answer. I mean, his
22 answer to the question is broader than just, oh, yeah, we --
23 you know, we do audits.

24 SPECIAL MASTER VANASKIE: I will allow it. I will
25 allow it.

1 Now we go to --

2 MS. LOCKARD: 172.

3 SPECIAL MASTER VANASKIE: -- 172. And the objection
4 is to the counter-designation. And I will allow the
5 counter-designation.

6 MS. LOCKARD: Okay. Thank you, Judge.

7 172, 18 to 21 is next.

8 SPECIAL MASTER VANASKIE: Yes. And you have an
9 objection.

10 MS. LOCKARD: Oh, I object because there was no answer
11 designated.

12 MR. STANOCH: I will agree to add the answer at
13 178-24. You can feel free to tell me that any time,
14 Ms. Lockard.

15 MS. LOCKARD: Okay, yeah.

16 SPECIAL MASTER VANASKIE: 178-24?

17 MR. STANOCH: Yes, sir.

18 SPECIAL MASTER VANASKIE: So we've got to go from 172,
19 line 21 to 178-24?

20 MR. STANOCH: Correct. With the intervening objection
21 will be removed, yes.

22 And, Judge, I know you know this. I am sorry.
23 Sometimes that's why a question and answer is broken up,
24 because when you're preparing clips, you have to tell the video
25 people. I am sorry it reads that way.

1 SPECIAL MASTER VANASKIE: I'm still having trouble
2 following this.

3 MS. LOCKARD: Yeah. The objection was at 172, 18 to
4 21, so the answer should be at line 24.

5 MR. STANOCH: I agree.

6 SPECIAL MASTER VANASKIE: And the answer is: I cannot
7 remember clearly.

8 Is that right?

9 MS. LOCKARD: That's right.

10 MR. STANOCH: Yes.

11 MS. LOCKARD: Yes. It sounded like you said page 178,
12 David, so I think that's why --

13 (Simultaneous speakers.)

14 MR. STANOCH: I'm so sorry, Judge.

15 SPECIAL MASTER VANASKIE: That's all right. It's in,
16 okay? We'll allow that.

17 MR. STANOCH: Yes, sir.

18 MS. LOCKARD: Okay. 185-13.

19 SPECIAL MASTER VANASKIE: 185-13.

20 MS. LOCKARD: And on the same line was 185-18. And
21 our objection was only starting at 185-22. Sorry, was -- let
22 me rephrase that.

23 Our objection was up to 185-22. So only up to 185-22.

24 MR. STANOCH: And just so I'm clear, the objection is,
25 Victoria, to the question, "in your experience as a Teva

1 auditor," is that the one?

2 MS. LOCKARD: Yes.

3 MR. STANOCH: Okay. Sorry. I just wanted to make
4 sure I was on the same page.

5 MS. LOCKARD: And so he's asking, you know, "In your
6 experience as a Teva auditor, is it appropriate to invalidate
7 out-of-specification results without a scientific
8 justification?"

9 He is asking Mr. Lin about the FDA's finding. And so
10 he's basically saying, you know, well -- I mean, in essence, do
11 you agree with FDA that this is appropriate, and it's not
12 appropriate to invalidate out-of-spec results.

13 And Mr. Lin is saying, look, regarding this situation,
14 I don't know the specifics, you know, however, on the FDA
15 website, you know, sometimes they will publish 483 reports
16 concerning similar issues.

17 But he's admitting that he's speculating because he
18 doesn't know under this circumstance with ZHP and what the FDA
19 findings are, he can't really speak to that situation. It's
20 the FDA --

21 SPECIAL MASTER VANASKIE: Your response, David?

22 MS. LOCKARD: Okay. I'll be --

23 MR. STANOCH: I will say, Your Honor, I specifically
24 asked him what he knew or thought based on his own personal
25 experience as a Teva auditor about a GMP issue that he would

1 encounter, that would be encountered, about invalidating
2 out-of-specification results. His answer is what it is. I'm
3 not sure what --

4 SPECIAL MASTER VANASKIE: I'll sustain the objection.
5 Let's go to 190, line 7 to 192, line 17.

6 MS. LOCKARD: I know this was a long designation.

7 SPECIAL MASTER VANASKIE: Yes.

8 MS. LOCKARD: Yeah, we'll withdraw that objection,
9 Your Honor.

10 SPECIAL MASTER VANASKIE: Okay. So that comes in.

11 MS. LOCKARD: That comes in.

12 MR. STANOCH: Two to go, Judge.

13 SPECIAL MASTER VANASKIE: Two to go.

14 And now we're up to page 229, lines 6 to 15.

15 MR. STANOCH: Yes, sir.

16 MS. LOCKARD: Okay. This is the for-cause audit in
17 2018, where we had discussed earlier about whether this was a
18 subsequent remedial measure, and you said it was not, you're
19 going to let it in.

20 SPECIAL MASTER VANASKIE: Right.

21 MS. LOCKARD: So I think -- I mean, we had relevance
22 based on 407, so --

23 SPECIAL MASTER VANASKIE: Yes, I think it comes in
24 then.

25 MS. LOCKARD: Yeah. So I was okay with that.

1 MR. STANOCH: Okay. So we're at the last -- so it
2 sounds like the last two, 229, 6 through 15; and 230, 7
3 through 23 are in.

4 MS. LOCKARD: No, we haven't dealt with the last one.

5 MR. STANOCH: Oh, I am sorry. I wasn't trying to pull
6 a fast one. I apologize.

7 SPECIAL MASTER VANASKIE: We haven't talked about
8 that, no.

9 MS. LOCKARD: So we object to 230, line 7 through 23.
10 So putting aside our argument about the audit itself,
11 Mr. Stanoch is asking this audit witness about a statement made
12 in a company document by Mr. Kumar, who is quoting from some
13 unidentified piece of literature. So we also have a hearsay
14 objection to this. Mr. Lin -- and a personal knowledge
15 objection.

16 Mr. Lin has not seen that piece of literature, it
17 doesn't meet the learned treatise exception, he's not an
18 expert, it hasn't been established as reliable authority. We
19 don't even know what this is. Mr. Lin doesn't know what this
20 is. He's testified he's never seen it. He says I'm not sure,
21 I'm not sure because I did not review this document.

22 And so all he can say is, well, that's what's listed
23 in the statement by Mr. Kumar in a company document about some
24 random piece of literature.

25 So I feel like this is very tenuous, it's misleading,

1 it calls for speculation on the part of this witness and
2 there's a hearsay objection.

3 SPECIAL MASTER VANASKIE: David?

4 MR. STANOCH: Thank you, Judge.

5 Mr. Lin is testifying about a document, an email and
6 attachment which he received in the ordinary course of
7 business. Right? That's what this is. This is not some
8 stranger document.

9 This is about the audit report that he's working on
10 for the audit that he went to on the ground with other audit
11 members in an email string that he's on and replying back and
12 forth to. Right? And this is an attachment to that email.

13 And it's simply confirming his receipt of this
14 document, and what it says in the audit report that he and his
15 team were putting together at the time. It's literally -- the
16 document at issue is an attachment called The Business Report
17 of Huahai -- right? -- about the nitrosamines. He was the one
18 who did the visit. He's already testified over a day and a
19 half that he was part of the group who went to the audit and
20 looked -- and did the for-cause audit, and he's confirming what
21 he received.

22 In terms of the hearsay objection, there's no hearsay
23 objection, Your Honor. We're not trying to put the article --
24 first of all, it's not just some strange document. It's cited.
25 There's a specific citation to a specific journal from 1983

1 about n-nitrosodimethylamine and it's formed by a reaction with
2 dimethylamine with a nitrosating agent.

3 He's citing a 1983 article, notice -- right? --
4 whether -- there is an article from 40 years ago talking about
5 this very reaction, which a colleague is sending to Mr. Lin and
6 others about their for-cause audit of ZHP about the formation
7 of nitrosamines.

8 MS. LOCKARD: But this is not something that was
9 discussed by Mr. Lin when he was on site doing his part of the
10 audit. This is when Mr. Kumar was pulling together information
11 to include in the audit summary, he pulled literature from
12 somewhere. And the literature isn't part of what Mr. Lin
13 relied on, it's this --

14 MR. STANOCH: That's not right.

15 MS. LOCKARD: Plaintiffs are using this to try to
16 argue for the truth of the matter that -- you know, what it
17 says, that it's formed by the reaction of dimethylamine. And
18 it's not -- I mean, nobody has shown that this piece of
19 literature meets the learned treatise exception. It's not been
20 established as reliable authority, no expert has talked about
21 this being a reliable authority. This is not even an expert.
22 So they shouldn't be using, you know, literature with a fact
23 witness.

24 SPECIAL MASTER VANASKIE: Yeah, I will sustain the
25 objection. And so --

1 MR. STANOCH: Judge, I'd like the opportunity to send
2 you the exhibit so you can see it, and potentially I can try to
3 argue to change your mind.

4 SPECIAL MASTER VANASKIE: You can send it to me and
5 try to change my mind, but I do think the hearsay objection is
6 well taken, so bear that in mind. I don't know what this
7 literature is, I don't know whether it would fall under the
8 learned treatise exception to the hearsay rule.

9 So at the present time, the objection is sustained
10 subject to being reconsidered after you send me the article or
11 whatever it is that's being relied upon.

12 MR. STANOCH: Very well, Your Honor. Thank you.

13 SPECIAL MASTER VANASKIE: All right. So that
14 concludes Mr. Pan Lin. I assume it's a mister.

15 MR. STANOCH: Yes.

16 MS. LOCKARD: Mister.

17 SPECIAL MASTER VANASKIE: Anything else for today?

18 MR. STANOCH: Yes.

19 SPECIAL MASTER VANASKIE: But we can't get to it.
20 We've gone long enough. I'm going to let our court reporter
21 go.

22 Thank you for your hard work today on this matter.
23 And I'll see you all tomorrow morning at 9:30, I
24 guess.

25 MR. STANOCH: Yes, Judge, some of us.

1 MS. LOCKARD: Thank you.

2 SPECIAL MASTER VANASKIE: All right. Thank you.

3 (Matter adjourned at 5:03 p.m.)

4 - - - - -

5

6 I certify that the foregoing is a correct transcript
7 from the record of proceedings in the above-entitled matter.

8

9 /S/ Sharon Ricci, RMR, CRR
10 Official Court Reporter

11

12 September 26, 2024
13 Date

14

15

16

17

18

19

20

21

22

23

24

25